IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

SIGHT SCIENCES, INC., Plaintiff, v. IVANTIS, INC., ALCON RESEARCH LLC, ALCON VISION, LLC, and ALCON INC., Defendants.	)	**Redacted - Public Version** C.A. No. 21-1317-GBW-SRF [redacted]

ALCON'S ANSWERING BRIEF TO SIGHT'S MOTIONS FOR SUMMARY JUDGMENT AND TO EXCLUDE EXPERT TESTIMONY

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I. NATURE AND STAGE OF PROCEEDINGS

Sight's summary judgment motions ignore abundant evidence contrary to its arguments, raise genuine issues of material fact, and fail to streamline issues for trial. D.I. 291 §§V-VIII. Sight's *Daubert* motions advance incorrect legal "rules" and raise issues best addressed through cross-examination, not exclusion. D.I. 291 §§X-XIII. Sight's motions should be denied.

II. SUMMARY OF THE ARGUMENT

1. Sight's Motion 1 parses patent claims into individual terms and requests "partial summary judgment of infringement" for each individual term. D.I. 291 § V.C. Infringement, however, is based on claims, not individual terms. The Court should reject Sight's procedurally flawed gambit, which would not streamline issues for trial and would risk confusing the jury and prejudicing Alcon. *See Adams v. Klein*, 2020 WL 2404772, at *4 (D. Del. May 12, 2020) (denying "partial summary judgment"). Sight's motion also fails because: (1) it seeks a finding that Alcon "infringes" terms in non-limiting preambles; (2) for method claim terms it alleges are "infringed" by a delivery system, it provides no evidence how the system meets the claims; and (3) it seeks a finding that Alcon "infringes" terms that render the claims indefinite or about which there are genuine issues of material fact.

2. Sight's Motion 2 is as improper as its first but seeks an infringement finding for different terms—the Block and Patency Limitations[1]—that Sight treats as synonymous. D.I. 291 §VI. The Block/Patency Limitation claims, however, are invalid as indefinite (D.I. 297 §III.C) and thus cannot be infringed. Moreover, as explained in Alcon's *Daubert* Brief (D.I. 294 §IX), Sight improperly relies on new constructions. *CommScope Techs. v. Dali Wireless*, 10 F.4th

[1] Sight's Brief (D.I. 291 at 14-17) refers to the "Block Limitation" as the "without substantial interference" limitation and the "Patency Limitation" as the "maintain the patency" limitation.

1289, 1299 (Fed. Cir. 2021). If Sight is permitted to rely on its new constructions, a genuine dispute exists whether fluid flows across the trabecular meshwork when Hydrus is implanted.

3. Sight's Motion 3 contends the iStent device is not prior art because "there were no public uses" of the device prior to June 26, 2006. D.I. 291 at 19. But Sight ignores the overwhelming evidence demonstrating public use and availability of the iStent device before June 26, 2006, which at a minimum demonstrates a dispute of material fact.

4. Sight's Motion 4 is contingent on Sight's Motions 1 and 2. Because those Motions should be denied, Motion 4 should also be denied.

5. Sight's motion to exclude Dr. Iwach's opinion should be denied because his opinion is supported by sufficient evidence and he is qualified to make it.

6. Sight's motion to exclude Dr. Izatt's and Dr. Tanna's opinions relying on certain models should be denied because (1) the models support their opinions under the Court's claim construction and (2) the models are helpful to the trier of fact.

7. Sight's motion to exclude Mr. Meyer and Drs. Becker and Iwach's opinions regarding non-infringing alternatives should be denied because (1) Drs. Becker and Iwach's opinions are based on sufficient and reliable evidence, and (2) Mr. Meyer and Drs. Becker and Iwach's opinions comport with settled law regarding the role of non-infringing alternatives in lost profits and reasonable royalty analyses.

8. Sight's motion to exclude Mr. Kunin's opinions should be denied because he opines only on PTO practice and procedure, consistent with the law and helpful to the jury.

III. SIGHT'S MOTIONS 1 AND 2 SHOULD BE DENIED BECAUSE "PARTIAL SUMMARY JUDGMENT" ON INCOMPLETE AND ISOLATED CLAIM TERMS IS IMPROPER, CONFUSING, AND PREJUDICIAL, AND GENUINE ISSUES OF MATERIAL FACT EXIST FOR THOSE TERMS

To prove patent infringement, Sight must prove every element of a patent claim is

satisfied. *Int'l Rectifier Corp. v. IXYS Corp.*, 361 F.3d 1363, 1369 (Fed. Cir. 2004). Neither of Sight's first two Motions alleges infringement of ***any*** patent claim. Rather, Sight plucks out individual elements, ignoring the surrounding language and other claim limitations, to allege that the Hydrus® Microstent, its delivery system, and instructions for use (collectively, "Hydrus") "meet" cherry-picked claim ***terms***. D.I. 291 §§V.C, VI. Sight's Motions are procedurally flawed: infringement requires proving ***all*** claim terms are present. *See Atl. Thermoplastics Co. v. Faytex*, 970 F.2d 834, 846 (Fed. Cir. 1992). Sight's attempted end-run around the summary judgment rules should be rejected. Sight's Motions are also substantively flawed—they conflate disputed terms in isolation from necessary context in a way that is both confusing and unfairly prejudicial, tasking the jury with mixing-and-matching "partial summary judgment" determinations within the broader context of the Asserted Claims. An infringement analysis requires analyzing the ***whole*** claim, and genuine disputes regarding Sight's selected terms preclude any such finding.

Sight cites only two authorities for its approach: Fed. R. Civ. P. 56(a) and *Synqor v. Artesyn Techs.*, 709 F.3d 1365 (Fed. Cir. 2013). D.I. 291 at 7. Neither supports Sight. Rather than "seek[] resolution of a 'part of a claim or defense' as intended by [Rule 56]," *Adams v. Klein*, 2020 WL 2404772, at *4 (D. Del. May 12, 2020), Sight seeks piecemeal factual findings about individual claim terms. "[T]here is little appetite within the Third Circuit for piecemeal Rule 56 adjudications that do not resolve at least one entire claim," here, patent infringement. *Chabot v. Walgreens Boots All.*, 2023 WL 2908827, at *22 (M.D. Pa. Mar. 31, 2023) (collecting cases); *see also City of Huntington v. AmerisourceBergen Drug*, 2021 WL 972295, at *3-4 (S.D. W. Va. Mar. 15, 2021) (similar and collecting cases). *Synqor* is also inapt. In that case, Defendants' ***only*** defense to infringement of ***the claims as a whole*** was based on a single term in each claim ("isolation" terms). 709 F.3d at 1379; *see also* Synqor's Brief, No. 2011-1191, 2012

WL 2086325, at *74-80. Because Defendants could not dispute infringement under the court's construction of the "isolation" terms, the Federal Circuit affirmed summary judgment that Defendants infringed ***the claims*** after holding the "isolation" terms were correctly construed. *Synqor*, 709 F.3d at 1379. That is not the case here, where Alcon disputes infringement based on numerous missing or indefinite claim terms,[2] not just the absence of a single term from a claim.

This case is more like *Adams*, where the court ***denied*** Plaintiffs' motion for partial summary judgment on "elements" of a cause of action because they were not "some sort of stand-alone elements which, once resolved, can be cut out of the case or stipulated to in some sensible fashion so that a portion of the trial is no longer necessary." 2020 WL 2404772, at *4. So, too, here. *See* D.I. 289-2. For example, each Asserted Claim recites the term "support," but "support" is never a standalone limitation—it always comprises additional features (*e.g.,* "having at least one fenestration" or "compris[ing] an arcuate member" or the amount of "surface area" it contacts when placed inside a hypothetical, rigid cylinder). *See, e.g.*, claim 1 of each Asserted Patent; *see also* D.I. 287 (construing "30% of C" as requiring a "slightly arcuate cylinder" estimate). Thus, even if an individual term like "support" were generically "met" (it is not, *see infra* §III.A and Resp. SOF1 ¶¶2, 10), Sight still must prove the specific additional limitations of the "support" are also met (*e.g.*, that it comprises an arcuate member). Granting Sight's motion that individual claim terms are "met" in isolation (*e.g.*, "support") risks confusing the jury into believing additional related limitations (*e.g.*, arcuate member) are also "met," prejudicing Alcon. Thus, like in *Adams*, Sight's "motion is better left undecided because (1) deciding it will do nothing to shorten or simplify the trial issues"—Sight still must prove all terms are met—"and

[2] *See Honeywell Int'l, Inc. v. Int'l Trade Comm'n*, 341 F.3d 1332, 1342 (Fed. Cir. 2003) (indefinite "claims, by definition, cannot be construed" and preclude an infringement analysis); 35 U.S.C. § 282(b)(3) (invalidity for indefiniteness a defense to infringement).

(2) the jury will be better able to decide the issues of the case without some partial judicial imprimatur on a very narrow part of the case." 2020 WL 2404772, at *4.

A. Sight's Motion 1 Should Be Denied Because It Seeks Summary Judgment of Infringement for Non-limitations, for Method Claims for Which It Cites No Evidence of Infringement, for Terms That Render the Claims Indefinite, and For Terms About Which Genuine Disputes of Material Fact Exist.

Sight's Motion 1 (D.I. 291 §§V.C.1-11)—which it seeks "partial summary judgment of infringement" of 19 different "claim elements" (D.I. 291 at 1-2)—should be denied for the five reasons set forth below.

1. Hydrus cannot "meet" non-limiting preamble terms.

Sight argues that Hydrus "meets" the preamble terms "device," "kit," and "reducing intraocular pressure" and this Court should therefore find infringement as a matter of law as to those "elements." D.I. 291 §V.C.1-2. These terms, however, do not limit the asserted claims. *See Allen Eng'g v. Bartell Indus.*, 299 F.3d 1336, 1346 (Fed. Cir. 2002) ("Generally, the preamble does ***not*** limit the claims."). Whether a preamble is limiting is a claim construction issue Sight never asked the Court to decide and therefore forfeited. *Catalina Market. Intern. v. Coolsavings.com*, 289 F.3d 801, 807-08 (Fed. Cir. 2002); Resp. SOF1 ¶¶ 3-4; *Aqua Connect v. TeamViewer*, 2023 WL 6387791, at *6 (D. Del. Sep. 29, 2023) (late claim construction waived).

If the Court entertains Sight's belated request, Sight cannot show the preambles are limiting. *See Catalina*, 289 F.3d at 808-09. ***First***, the "device" and "kit" preambles are not limiting because the body of the claims provides a "structurally complete invention." *See id.* at 808 ("[A] preamble is not limiting where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention."). For example, the preamble of '482 claim 1 recites a "device" and the body provides the complete structure of that device, which is a "support" with certain features. The word "device" in the

preamble "merely gives a descriptive name to the set of limitations in the body of the claim that completely set forth the invention," and is therefore not a claim limitation that can be "met." *IMS Tech. v. Haas Automation*, 206 F.3d 1422, 1434 (Fed. Cir. 2000).

Second, the language "for reducing intraocular pressure" in the preamble of the "device," "kit," and method claims is not a limitation because it only states the "purpose or intended use" without itself reciting ***any*** features. *Catalina*, 289 F.3d at 808. As noted above, the body (not the preamble) of the device and kit claims recite the features of the device. The preamble in the method claims that recites the "for reducing intraocular pressure" term ('482 claim 63; '361 claim 1; and '328 claim 1) is non-limiting because the method steps in the body of these claims "are performed in the same way regardless [of] whether or not the patient experiences a reduction [in intraocular pressure]." *BMS v. Ben Venue Labs.*, 246 F.3d 1368, 1375 (Fed. Cir. 2001) (preamble "for reducing hematologic toxicity" non-limiting and "merely expressing a purpose"). As non-limitations, the "device," "kit," and "reducing intraocular pressure" preambles are not a "part of" a claim on which summary judgment can be granted. Similarly, Sight mentions other preamble terms ("glaucoma" or "method for treating an eye condition") without providing any supporting argument. D.I. 291 at 2. Not only are these arguments waived, *John Wyeth & Bro. v. CIGNA*, 119 F.3d 1070, 1076 n.6 (3d Cir. 1997), they also fail on the merits, as these terms, too, merely express a "purpose or intended use." *BMS*, 246 F.3d at 1375. Sight's motion that these various non-limitations are "met" should be denied. Fed. R. Civ. P. 56(a).

2. Sight cites no evidence that Hydrus "meets" the "introducer" terms in the method claims.

Sight seeks "partial summary judgment of infringement" that Hydrus—a physical thing—"meets" the "introducer" elements in certain asserted ***method*** claims, but Sight provides no evidence to show how the Hydrus delivery ***system*** satisfies the ***method*** steps. D.I. 291 §V.C.6;

see also D.I. 289-2 at 2 (citing '742 patent claims 19 and 20, '328 patent claim 1, and "*see also* '361, claim 1"); D.I. 291 at 9-10. "A method claim is directly infringed only by one practicing the patented method." *Joy Techs. v. Flakt*, 6 F.3d 770, 775 (Fed. Cir. 1993); *see also* 35 U.S.C. §§271(a)-(c). Thus, Sight must prove that Alcon (or another entity) actually performs every step of the claimed method. "[I]t is not enough to simply show that a product is capable of infringement; the patent owner must show evidence of specific instances of direct infringement." *Fujitsu Ltd. v. Netgear*, 620 F.3d 1321, 1329 (Fed. Cir. 2010).

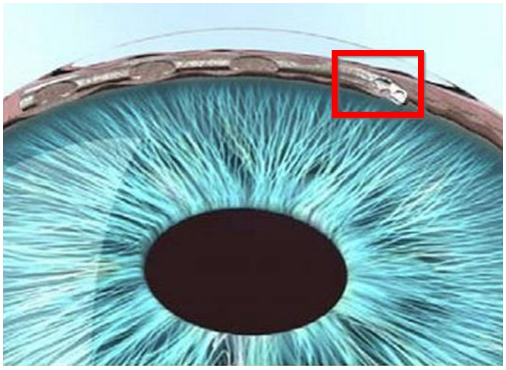
Sight relies solely on the physical features of the Hydrus delivery system (*e.g.*, that it has a "pusher assembly" or "tubular cannula") (D.I. 291 at 10), but provides no allegations of method performance—either by Alcon or a third party—of the claims requiring "introducer" elements. *Joy Techs.*, 6 F.3d at 775; *see also Fujitsu*, 620 F.3d at 1329. Indeed, Sight's "Facts" do not allege that (much less how) the Hydrus system performs the claimed "introducer" method steps, nor does Sight identify anyone allegedly performing the steps. *See* D.I. 290-1 ¶ 8. Sight's Motion fails on the merits and its arguments forfeited. *See John Wyeth*, 119 F.3d at 1076 n.6.

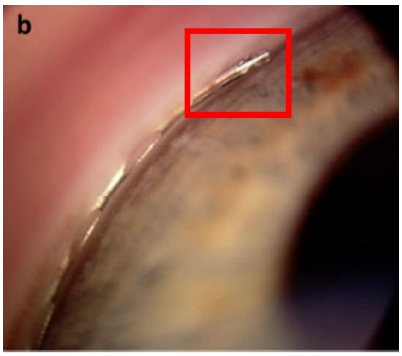
3. Sight generically alleges Hydrus "meets" the "support" limitations, but provides no specifics regarding what feature of Hydrus "props" open Schlemm's canal.

Sight generically alleges Hydrus "meets" every "support" limitation across all 86 Asserted Claims without identifying what part of Hydrus is "a prop" or "a structure that props something open." *See* D.I. 287 §V.C.1. This amounts to no more than an "argument[] raised in passing…but not squarely argued," and is therefore "considered waived." *John Wyeth*, 119 F.3d at 1076 n.6. Sight's generic allegation also illustrates the inappropriateness of its piecemeal approach to infringement of isolated terms, because the claimed "support" is always tied together to disputed features. *Atl. Thermoplastics*, 970 F.2d at 846. For example, in some claims, the "support" must include "an arcuate member" (*see, e.g.*, '443 cl. 1), a term not in Sight's Motion

because it is disputed. D.I. 298-19 ¶¶ 137-148; Resp. SOF1 ¶¶2, 10. A finding that Hydrus "meets" the "support" term would not resolve the infringement question because that analysis must consider the additional claimed features of the "support," like the "arcuate member." Finding "support" met in isolation would serve only to complicate trial and confuse the jury.

Sight incorrectly contends Alcon's expert, Dr. Iwach, "offered no opinion" regarding non-infringement for the "support" term. D.I. 291 at 8. But Dr. Iwach offered several opinions regarding "support," including that a portion of Hydrus's inlet is not a "support" and that Dr. Downs failed to explain how certain other portions of Hydrus meet the "support" limitation. *See* D.I. 298-19 ¶¶ 96-105. Dr. Iwach's opinion that the inlet portion of Hydrus sitting in the anterior chamber does not meet the "support" term is unrebutted: that portion is ***not*** in Schlemm's canal and therefore cannot prop it open. *Id.* ¶¶ 96-98. In fact, the Hydrus inlet bypasses the trabecular meshwork tissue and undisputedly sits in the anterior chamber without propping ***anything*** open:





D.I. 298-19 at 44-45. Sight's single word selection from its claims ignores the remainder of the surrounding claim language and "will do nothing to shorten or simplify the trial issues," warranting denial of its Motion. *Adams*, 2020 WL 2404772, at *4.

4. Hydrus cannot "meet" the indefinite "30% of C" limitation.

Sight also argues that Hydrus "meets" the "30% of C" term that, under the Court's construction, requires estimating the amount of surface area a support will make with Schlemm's

canal when implanted assuming Schlemm's canal is a hypothetical "slightly arcuate cylinder." D.I. 291 §V.C.11; D.I. 287. Hydrus, however, cannot "meet" this term because the claims reciting it are indefinite, as discussed below. *See Netgear v. Ruckus Wireless*, 5 F. Supp. 3d 592, 611 (D. Del. 2013) (denying summary judgment of infringement because claims were indefinite); *Commil USA v. Cisco Sys.*, 575 U.S. 632, 644 (2015).

Sight's assertion that Hydrus only makes "'point contact' with the arcuate (*i.e.*, curved) cylinder representing Schlemm's canal," D.I. 291 at 13, demonstrates the indefiniteness of the term. ***First***, Schlemm's canal is not "represent[ed]" by an "arcuate cylinder"—the canal can be collapsed, stretched, and/or have a variety of cross-sectional shapes that are not circular. *See, e.g.*, D.I. 298-1, '482 Fig. 5A; 1:53-59, 8:31-41 ("narrowed" or "collapsed" canal); D.I. 119-20, 31:6-18, 35:17-19; D.I. 119-21 ¶ 36.

Second, the 30% of C term as construed provides nonsensical results that render the claims invalid as indefinite. "A claim that is nonsensical or requires an impossibility is indefinite as a matter of law." *Koki Holdings v. Kyocera Senco Indus. Tools*, 2021 WL 1092579, at *1 (D. Del. Mar. 22, 2021). Sight alleges Hydrus is partially implanted into Schlemm's canal to "prop" open the canal (D.I. 291 at 7), but at the same time contends Hydrus makes near-zero percent contact with the "arcuate cylinder" supposedly approximating Schlemm's canal. *See* D.I. 298-14, Downs Op. Rep. ¶ 140 (calculating Hydrus makes 0.00029-0.00044% contact with hypothetical cylinder). When implanted into the flexible Schlemm's canal, Hydrus rests up against its inner wall. *See, e.g.*, D.I. 298-19 at 44-45 (depicting implanted Hydrus). It makes no sense that Hydrus could rest against the inner wall of Schlemm's canal, yet make essentially ***no contact*** with the canal it allegedly props open. This nonsensical outcome confirms the "30% of C" term is indefinite. *See Trustees of Columbia Univ. v. Symantec*, 811 F.3d 1359, 1366-67 (Fed. Cir. 2016)

("The claims are nonsensical in the way a claim to extracting orange juice from apples would be, and are thus indefinite"); *Synchronoss Techs. v. Dropbox*, 987 F.3d 1358, 1366-67 (Fed. Cir. 2021). Summary judgment that this indefinite term is "met" should therefore be denied, and summary judgment of indefiniteness should be granted in Alcon's favor (D.I. 297 §III.C).

5. The remaining terms Sight alleges are "met" are standalone terms for which summary judgment is improper.

Sight also seeks "partial summary judgment of infringement" of seven other individual terms, again in isolation from additional limitations surrounding those terms. D.I. 291 §§V.C.3-5, V.C.7-10. Many of the terms, however, appear in dependent claims,[3] which can only be infringed if the independent claims are also infringed. *Wahpeton Canvas v. Frontier*, 870 F.2d 1546, 1553 (Fed. Cir. 1989). Alcon disputes that the independent claims are infringed, including because of Sight's moving-target infringement allegations for terms like "substantial interference." *See* §III.B below. Summary judgment therefore should be denied because these individual terms and dependent claims are not "stand-alone elements which, once resolved, can be cut out of the case or stipulated to in some sensible fashion so that a portion of the trial is no longer necessary." *Adams*, 2020 WL 2404772, at *4; *Chabot*, 2023 WL 2908827, at *22.

The scope of the claims is also disputed, which further demonstrates the flaws in Sight's piecemeal approach. *Adams*, 2020 WL 2404772, at *4. For example, Sight's expert changed his opinion on the plain meaning of the terms "fenestration," "longitudinally insertable," and "implantable circumferentially" in his Rebuttal Report to try to avoid the prior art. *See* D.I. 294

[3] *See* D.I. 291 §§ V.C.7-10 (arguing dependent claim limitations "[is made from / comprises] a shape memory [material / alloy]," "nickel titanium alloy," or "biocompatible metal." ('443, cls. 21, 23, 24, 27; '482, cls. 8, 10, 11, 39, 41, 42, 77, 79, 80; '742, cls. 6-9; '328, claim 25); "support comprises fluted edges." ('482, cls. 5, 36, 68); "the support is flexible" ('443, cl. 52; '742, cl. 15); and "further comprising instructions on using the kit." ('443, cl. 59)).

at 26 (moving to exclude Sight's expert's amended construction of "fenestration"); *id.* at 25-26 (moving to exclude Sight's expert's amended construction of the "insertable" and "implantable" terms). Because a "patent may not, like a nose of wax, be twisted one way to avoid anticipation and another to find infringement," *CommScope Techs. v. Dali Wireless*, 10 F.4th 1289, 1299 (Fed. Cir. 2021), Sight's request that individual terms are "met," including those for which it takes inconsistent positions, should be denied.

B. Sight's Motion 2 For Partial Summary Judgment of Infringement That the "Maintain The Patency" And "Block" Limitations Are "Met" Is Premised on Inconsistent Claim Constructions and Should Be Denied.

Sight's "Motion No. 2" should be denied for the same reason Sight's "Motion No. 1" should—it seeks summary judgment of "infringement" on two individual claim terms, a "piecemeal Rule 56 adjudication[]" for which there is "little appetite within the Third Circuit." *Chabot*, 2023 WL 2908827, at *22 (collecting cases); *see* §III above. Moreover, when arguing that Hydrus infringes the "maintain the patency" and "Block" (collectively, "'Patency/Block'") Limitations,[4] Sight has advanced inconsistent claim construction positions that present genuine disputes of fact inappropriate for resolution at this stage. Fed. R. Civ. P. 56(a).

In an effort to prove infringement of the Patency/Block Limitations, Sight and its expert originally argued that "Hydrus keeps Schlemm's canal at least partially unobstructed with respect to the flow of aqueous through the trabecular meshwork," *i.e.*, permits flow. D.I. 298-14 ¶ 86 (Patency), ¶ 94 (Block). But when attempting to avoid the prior art (which clearly meets the claim limitations under Sight's expert's original infringement analysis), Sight generated a new argument that would ***require***, rather than ***permit***, flow across the trabecular meshwork. D.I. 298-

[4] Sight presents the same evidence for both limitations. D.I. 291 at 17 ("does not significantly block" is "thus related to the 'maintain the patency term.'"); *id.* (relying on same evidence for "maintain the patency" and Block Limitation). As such, Alcon addresses them together.

24, 9/28 Downs Tr. 107:13-21 ("the 'substantial interference' term ***requires*** some flow across—through the trabecular meshwork"); D.I. 298-23, 9/22 Downs Tr. 85:15-86:8, 208:12-211:13; D.I. 298-15, Downs Reb. Rep. ¶¶146-192, 247-279, 375-412, 464-491, 538, 542-576; *see also* D.I. 294 at 23-25. A party's own theories relating to the scope of claim terms for purposes of invalidity that are inconsistent with that party's infringement theories ***itself*** creates a genuine issue of fact that warrants denial of a motion for summary judgment. *CommScope*, 10 F.4th at 1299 (reversing denial of JMOL of non-infringement). But even under Sight's improper new construction of the Block Limitation, a genuine dispute of material fact exists regarding whether flow actually occurs across the trabecular meshwork when Hydrus is implanted. Sight's Motion that these limitations are "met" or "infringed" should therefore be denied.

1. Sight's inconsistent construction of "Block" and "Patency" Limitations improperly applies a different standard to infringement and invalidity.

The Court adopted Sight's and its expert's advocated-for construction of the "Block" Limitation claims, construing these terms to mean "the support does not significantly block either fluid outflow from the trabecular meshwork or fluid outflow to the collector channels." D.I. 287 at 1. The Court rejected indefiniteness of the Block Limitation because it "agree[d] with [Sight] that a skilled artisan would evaluate whether a support 'substantially interferes' or 'significantly blocks' fluid flow in the eye 'by determining whether an increase in aqueous outflux (and therefore, a decrease in IOP) has been achieved by the support.'" D.I. 273 at 6-7. The Court's construction also requires only that a device ***permit*** (*i.e.*, not block) fluid outflow to the extent flow exists; it does not ***require*** fluid outflow in any specific location. Now, however, Sight's expert asserts that increased outflow/decreased IOP are ***insufficient*** to determine whether a device significantly blocks fluid flow. According to Dr. Downs, "flow has to occur" specifically through the trabecular meshwork. D.I. 298-24 at 107:13-21 ("I believe the

'substantial interference' term ***requires*** some flow across—through the trabecular meshwork."); D.I. 298-23 at 85:15-86:8, 208:12-211:13; D.I. 298-15 at ¶¶146-192, 247-279, 375-412, 464-491, 538, 542-576; *see also* D.I. 294 at 23-25.

Similarly, for the "Patency" Limitations, Sight's expert improperly proposes a ***permissive*** construction: "the support operates to keep the canal at least partially unobstructed to transmural flow, ***such that fluid can*** 1) exit through the trabecular meshwork; 2) traverse the canal; and 3) drain via the collector channels." D.I. 291 at 14. Yet, Dr. Downs admits that in his opinion flow across the trabecular meshwork is ***required*** to meet the "Patency" Limitation. D.I. 298-23 at 66:3-22 (Q: So you're reading a requirement into the word 'operate' that does in fact require that fluid must exit through the trabecular meshwork --. A: Yes.).

Lacking any evidence that fluid actually flows across the trabecular meshwork when Hydrus is implanted, Sight reverses course to omit its own proposed requirement that flow actually occurs in a specific location. *See* D.I. 291 at 17 ("evidence…demonstrates that Hydrus ***permits*** fluid outflow."); *see generally* D.I. 298-14. Sight's about-face is a transparent attempt to lower its burden to prove infringement according to one construction (***allowing*** flow), while raising Alcon's burden to show invalidity according to another construction (***requiring*** flow) as shown in the table below. *See CommScope*, 10 F.4th at 1299 (cannot "twist[] [patents] one way to avoid [invalidity] and another to find infringement").

Sight's Infringement Position	**Sight's Invalidity Position**
Hydrus's "open scaffold design minimizes resistance to aqueous outflow through Schlemm's canal and is also designed not to interfere with the collector channel openings. The three fenestrations along the length of the Hydrus also provide outflow pathways for aqueous humor to traverse the trabecular meshwork into the canal." D.I. 298-14, Downs Op. Rep. ¶ 95.	"In other words, mere inclusion of pores or fenestrations would not, as Dr. Tanna's report appears to assume, necessarily produce flow through the trabecular meshwork." D.I. 298-15, Downs Reb. Rep. ¶ 173.

Sight's Infringement Position	Sight's Invalidity Position
"[L]aboratory testing has repeatedly and consistently shown that the Hydrus increases outflow facility in human eyes—an outcome that could not have been achieved if the Hydrus significantly blocked fluid outflow either across the trabecular meshwork or into the collector channels." D.I. 298-14, Downs Op. Rep. ¶ 97.	"While the larger purpose of Gharib's [prior art] device may be to increase flow of aqueous humor from the anterior chamber to the collector channels, it does so by 'utilizing the entire outflow pathway *except for the trabecular meshwork*, which is bypassed by the trabecular shunt….' In bypassing the trabecular meshwork, or only encouraging fluid to flow through the lumen of the inlet section of Gharib's shunt, Gharib's device would significantly block fluid outflow from the trabecular meshwork." D.I. 298-15, Downs Reb. Rep. ¶ 153 (emphasis in original)

2. Even applying Sight's new constructions, substantial evidence exists for a jury to find Hydrus does not infringe.

If the Court adopts Sight's improper new claim construction for the Block/Patency Limitations, requiring actual membrane-specific flow (which it should not), a genuine dispute of material fact exists as to whether the Hydrus meets these limitations. Sight's expert offers opinions that Hydrus ***allows*** fluid to flow across the trabecular meshwork and through the windows of the device, but fails to offer ***any*** evidence that fluid actually flows through the windows *in vivo*, a proposition at odds with the evidence (Add'l SOF2 ¶¶1-3) and with which Alcon's expert disagrees. Resp. SOF2 ¶¶4-5, 7-9; *see Cross Med. Prods v. Medtronic Sofamor Danek*, 424 F.3d 1293, 1309-19 (Fed. Cir. 2005) (vacating summary judgment of infringement where genuine dispute existed). Indeed, Dr. Iwach refutes the actual-flow supposition and opines that aqueous fluid will instead flow along the path of least resistance, which for Hydrus is the inlet that ***bypasses*** the trabecular meshwork. Resp. SOF2 ¶¶4-5, 7; Add'l SOF2 ¶¶1-3.

Sight's argument that it has shown, as a matter of law, that Hydrus "meets" the Block Limitation because Alcon did not furnish "fluid dynamics calculations or modeling[] to show that there would be no aqueous outflow through the trabecular meshwork once Hydrus was implanted" (D.I. 291 at 14) ignores that Sight, not Alcon, bears the burden to prove infringement.

See Medtronic v. Mirowski Fam. Ventures, 571 U.S. 191, 193-94 (2014). Sight's expert did not conduct or cite any studies where flow data was collected, and he performs no fluid dynamics calculations or modeling. D.I. 298-19, Iwach Reb. Rep. ¶¶ 108, 113. Sight falls short of its infringement burden and its motion for summary judgment of infringement of the Patency/Block Limitations should therefore be denied. *See Olaplex v. L'Oreal USA*, 845 F. App'x 943, 951 (Fed. Cir. 2021) (reversing summary judgment where expert presented no independent testing).

Sight cannot have it both ways: lowering the bar for infringement of the Patency/Block Limitations by not showing membrane-specific flow when Hydrus is implanted and simultaneously raising the bar for invalidity to require membrane-specific flow in the prior art. *CommScope*, 10 F.4th at 1299. And even if the Court were to adopt Sight's new construction, Sight marshaled ***no*** evidence of *in vivo* flow across the membrane when Hydrus is implanted. Accordingly, Sight's Motion 2 should be denied. *See Cross Med. Prods*, 424 F.3d at 1309-19.

IV. SIGHT'S MOTION 3 FOR SUMMARY JUDGMENT SHOULD BE DENIED BECAUSE, AT A MINIMUM, A DISPUTE OF MATERIAL FACT EXISTS WHETHER iSTENT WAS PUBLICLY AVAILABLE PRIOR TO JUNE 2006.

Sight contends for the first time[5] on summary judgment that the physical iStent device[6] ("iStent") was not "'in public use' or 'publicly accessible' in the U.S. prior to June 26, 2006," and thus is not prior art. D.I. 291 at 19. Whether a product was publicly accessible is a fact question that requires analysis of "the totality of the circumstances." *Netscape Commc'ns v. Konrad*, 295 F.3d 1315, 1320 (Fed. Cir. 2002); *In re NTP, Inc.*, 654 F.3d 1279, 1296 (Fed. Cir. 2011). Sight, as movant, must show that no genuine issues of material fact exist. *See 8x8 v.*

[5] Alcon's Interrogatory No. 8 asked Sight to describe "the basis of any contentions that the cited Prior Art…does not constitute Prior Art." D.I. 298-65; *see* Add'l SOF3 ¶1. In response, Sight failed to include any contention that the iStent device is not prior art. *Id*.

[6] Sight only challenges public availability of iStent, not publications about it. D.I. 291 at 19–20.

United States, 854 F.3d 1376, 1380 (Fed. Cir. 2017). Sight cannot meet its burden.

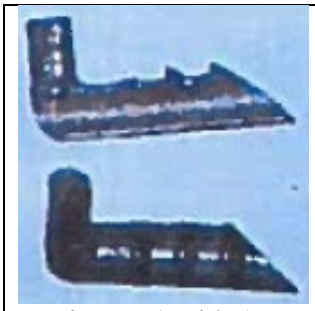
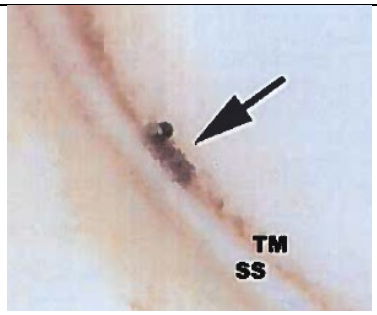
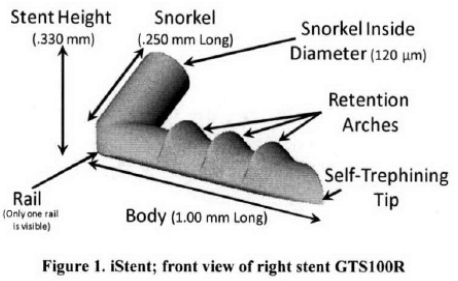
It is undisputed the iStent was distributed as part of clinical trials at least as early as 2003. Sight nonetheless argues that because participants in clinical studies may, as a general matter, be subject to confidentiality requirements, this dissemination of iStent does not qualify as a public use. That clinical trials as a general matter may be subject to confidentiality provisions says nothing about whether the iStent's were. Alcon also adduced substantial evidence demonstrating the device was publicly available. Indeed, Sight concedes numerous publications describing the iStent—many containing photographs and descriptions of the device—were publicly available before June 26, 2006. The breadth of this dissemination, and the detail with which the iStent was described, create a dispute of material fact for trial.

A. Substantial Evidence Demonstrates the iStent Was Distributed Without Confidentiality Restrictions Before June, 26 2006.

Sight concedes clinical trials for the iStent began at least as early as 2003. *See* D.I. 295-5, Parrish Reb. Rep. ¶60. Sight also does not dispute iStent was distributed to clinicians as part of these studies. *Id.*; Ex. 21, Parrish Tr. 162:7-11. Sight only contends these studies ***may*** have required confidentiality. D.I. 291 at 20-22. The evidence demonstrates otherwise.

By 2004, investigators had published initial iStent study results. For example, it is undisputed that Bahler's article entitled "Trabecular Bypass Stents Decrease Intraocular Pressure in Cultured Human Anterior Segments," which was published in the American Journal of Ophthalmology in December of 2004, showed photographs of the iStent device, including implanted in Schlemm's canal, and described a cadaveric eye study of iStent. D.I. 298-41 at 866-867; D.I. 291 at 20. Bahler also described iStent's design and dimensions down to the micrometer (μm), how it is implanted into Schlemm's canal, and its weight to the milligram. D.I. 298-41 at 867 ("Methods"). Bahler's detailed instructions and images mirror iStent's Directions

for Use (DFU), which Sight does not dispute clinical trial physicians would have received:

 iStent (Bahler)	 iStent within Schlemm's canal (Bahler)	 Figure 1. iStent; front view of right stent GTS100R iStent (DFU)

D.I. 298-41 at 866-867; D.I. 292-41 at 1; D.I. 292-45 at 257:18-25; Ex. 21 at 162:7-11; Ex. 15 at 189:7-190:7 (admitting figure in Bahler has same curvature as DFU figure). Another researcher, Dr. Samuelson, also published an article describing the iStent titled "The New Glaucoma Surgeries" in a 2004 issue of Glaucoma Today, explaining the iStent is placed via an ab-interno, transcameral approach. *See* D.I. 292-39 at 942.

Indeed, by 2005, Glaukos's iStent was well-known in the industry. Paul Badawi, named co-inventor of the Asserted Patents, admitted he was aware of iStent ***prior*** to his alleged conception of the alleged inventions in June 2006. *See* Ex. 12 at 41:14-24. Glaukos also presented iStent at the Annual Meeting of the Association for Research and Vision in Ophthalmology ("ARVO"), which Sight's expert, Dr. Downs, testified draws thousands of attendees and includes device demonstrations. D.I. 298-24 at 174:16-22; 175:18-176:23; 178:21-179:16; *see also* Ex. 55 at 515 (9,700 professionals attended ARVO 2005). Dr. Tanna testified he saw "at least one presentation on iStent" at ARVO 2005. Ex. 22 at 59:8-59:14. Dr. Downs testified that Glaukos discussed iStent at ARVO 2005 and published the results of a 51-patient prospective study of iStent. Ex. 15 at 180:11-184:24; *see also* Ex. 52 at 290-91. Glaukos continued to enroll patients in clinical trials in 2005. *See* D.I. 292-40 at 954 (describing results of a study that began April 2005); D.I. 295-5, Parrish Reb. Rep. ¶60. And iStent continued to be the

subject of industry presentations. *See* Ex. 54 at 493; Ex. 22, Tanna Tr. 58:12-59:14.

In March 2006, Dr. Sherwood, a principal investigator in an iStent trial, published "Rethinking Glaucoma Surgery: Aqueous within the Eye" on the American Academy of Ophthalmology website ("Sherwood"). Like Bahler, he included photos of the iStent device. Ex. 51 at 285-86, 288. Sherwood also explained how to insert iStent in patients, consistent with iStent's DFU. *Compare id. with* D.I. 292-41 at 1, 4, 6.

B. Sight Fails to Establish No Dispute of Material Fact Exists.

Sight argues the iStent clinical studies—described in Bahler and Samuelson 2011—do not show public use because participants in clinical studies ***generally may be*** subject to confidentiality requirements. But Sight identifies no such confidentiality provisions ***for iStent***, and the exhaustive disclosures of the device, including pictures of it, its physical design, and implantation technique are inconsistent with confidentiality restrictions.[7] *See* §IV.A; *Minerva Surgical v. Hologic*, 59 F.4th 1371, 1380 (Fed. Cir. 2023) (rejecting argument that general policy of confidentiality showed lack of public use where record suggested no confidentiality measures were actually taken). Indeed, the publicity surrounding iStent (including Bahler, Sherwood, and Samuelson) shows the ***opposite***: that Glaukos did not restrict the public dissemination of the iStent before Sight's claimed 2006 priority date. *See* §IV.A; *Minerva*, 59 F.4th at 1379-80 (detailed feedback from trade show indicated no enforcement of company confidentiality policy). Sight does not even address Samuelson 2004, the 2005 ARVO presentation, or Sherwood—all disclosed during discovery—which further demonstrate the lack of confidentiality restrictions placed on the iStent. *See* Resp. SOF3 ¶4.

[7] Similarly, whether Dr. Tanna personally had access to the iStent device is immaterial; ***others*** had access to the iStent with no apparent restrictions. *See* §IV.A.

The cases Sight relies on are inapposite. In *Eli Lilly* and *Delano Farms*, there was evidence that confidentiality restrictions applied in the relevant clinical trials, evidence that does not exist here. *See Eli Lilly and Co. v. Zenith Goldline Pharma*., 471 F.3d 1369, 1380-81 (Fed. Cir. 2006); *Delano Farms v. Cal. Table Grape Comm'n*, 778 F.3d 1243, 1248 (Fed. Cir. 2015); *see also Minerva,* 59 F. 4th at 1380, n. 4 (distinguishing *Delano Farms* based on the existence of evidence of confidentiality measures). Even *Dey v. Sunovion Pharm.*, which Sight relies on, supports denying Sight's motion because Alcon's unrebutted evidence discussed above, at a minimum, creates "[i]mportant issues of [disputed] fact." 715 F.3d 1351, 1356 (Fed. Cir. 2013) (reversing finding of summary judgment because of existence of disputed material facts). *Bruckelmeyer v. Ground Heaters* is likewise inapposite, because it dealt with whether a prior art patent application was sufficiently "classified and indexed" to be "publicly accessible," 445 F.3d 1374, 1378-79 (Fed. Cir. 2006), not whether a device disseminated to POSAs as part of clinical trials lacking any indication of confidentiality was "publicly accessible." In any event, the Federal Circuit in *Bruckelmeyer* found that the application ***was*** "publicly accessible." *Id*. This case is more like *Pronova Biopharma v. Teva Pharm.*, 549 Fed. App'x 934, 942-943 (Fed. Cir. 2013), where the Federal Circuit found public use when pharmaceutical samples were sent to a physician with no confidentiality restrictions or limitations on using the product with hopes of engaging him in clinical studies.

Finally, Sight's assertion that Dr. Tanna admitted the iStent was not publicly available before June 26, 2006 is also incorrect. In the cited excerpt, Dr. Tanna responded to whether there was "public prior use" under ***Sight's counsel's definition***, which used the legal term of art "experimental use," without clarifying for Dr. Tanna—who is not a lawyer—what "experimental use" included. D.I. 292-45 at 226:21-227:8; *Lough v. Brunswick Corp.*, 86 F.3d 1113, 1120 (Fed.

Cir. 1996) ("whether a use is 'experimental' [is] a question of law"). Sight's attempted "gotcha" falls apart in light of Dr. Tanna's complete testimony that further confirms the iStent was publicly available before June 26, 2006:

- "***In 2006 I showed residents the iStent and told them about iStent implantation*** as an ab-interno approach that was on the horizon." D.I. 292-45 at 80:3-6.
- "***There were probably 25 different centers that were participating in the clinical trial for iStent***. And so ***there were a lot of people who knew and were talking about iStent***, showing pictures of it, showing video of it. And so ***there was no secret of iStent in 2006***." Ex. 22 at 238:10-16.
- "[***W]e knew a lot about the iStent prior to FDA approval***. ***Bahler … shows what the iStent looks like***…[T]here may have been promotional-type materials that people were using to show what the iStent looked like.… ***[Glaukos] was very proud about what was developing and definitely was talking about it***. And at national meetings, there were people… giving lectures about the device." Ex. 22 at 58:12-59:3.
- "***[The iStent] was publicly available [before 2006]*** in that its physical characteristics were widely known, as described in Bahler and as described at many meetings. And ***it was available for clinical trials***." D.I. 292-45 at 258:1-8.

Sight's hand-waving about hypothetical confidentiality provisions and cherry-picked deposition quotes cannot change the abundant evidence demonstrating that the iStent was publicly available prior to June 26, 2006. At most, Sight's arguments demonstrate issues of material fact to be decided at trial, and summary judgment should be denied.

V. SIGHT'S "CONDITIONAL" MOTION 4 SHOULD BE DENIED

Sight's Motion 4 is contingent on its Motions 1 and 2. Because Sight's Motions 1 and 2 should be denied for the reasons discussed above (§III), so too should Sight's Motion 4.

VI. DR. IWACH'S TRANSITION-ZONE OPINION IS ADMISSIBLE

Dr. Iwach opines that a portion of the Hydrus (referred to as the "transition zone") does not meet the "arcuate member" term of claims of the Asserted Patents because (1) Dr. Downs relied on an outdated drawing and thus failed to prove the term is met, and (2) the Hydrus's current drawing shows the transition zone is not curved. D.I. 298-19 ¶¶ 90, 137-141. Sight seeks

to exclude Dr. Iwach's opinion because (1) other evidence allegedly supports a contrary conclusion, and (2) Dr. Iwach is not an engineer. D.I. 291 at 25-30. Sight's criticisms fail because they are either irrelevant to the Rule-702 analysis, factually inaccurate, or both.

First, Sight's arguments regarding allegedly competing evidence are irrelevant to the Rule-702 inquiry. Whether an expert "relied on the best data in forming his opinions is a question for the jury." *Allscripts Healthcare v. Andor Health*, 2022 WL 3021560, at *15, 17 (D. Del. July 29, 2022). As Sight's own case explains, "what [an expert] did and did not observe, or what he did or did not consider" is "fodder for cross examination, not…*Daubert*." *Integra Lifesci. v. HyperBranch Med. Tech.*, 2018 WL 1785033, at *3 (D. Del. Apr. 4, 2018); *Wright v. Elton*, 2022 WL 1091280, at * 3 (D. Del. Apr. 12, 2022). Even "flatly contradict[ory]" evidence "goes to weight and credibility," not admissibility. *Godreau-Rivera v. Coloplast*, 598 F. Supp. 3d 196, 213-14, 207 (D. Del. 2022). If Sight believes conflicting evidence exists, it can present it.

In any event, the evidence Dr. Iwach relies on is sufficient to support his opinion. Dr. Iwach relies on the current engineering drawing of the Hydrus (C00151 Revision J (Ex. 39, IVANTIS_SS_00000772)), which is the sole document Ivantis's manufacturer uses to produce the Hydrus according to the specified shape and dimensions. Ex. 43, IVANTIS_SS_00039039 at 39051, 39053 (noting that Hydrus provides the "current drawing with each purchase order" to the manufacturer); Ex. 42, IVANTIS_SS_00136401 at 136418, 136420 (same); Ex. 19, Kimball Tr. 81:6-82:9; D.I. 298-19 Iwach Reb. Rep. ¶¶137-141; Ex. 17, Iwach Tr. 199:2-200:2. Sight's expert inexplicably relied on an inaccurate and outdated version of the Hydrus drawing (C00151 Rev. G) to assert that the Hydrus's transition zone is curved, concluding it satisfies the "arcuate member" term. *See, e.g.*, D.I. 298-14 Downs Op. Rep. ¶123 (citing IVANTIS_SS_00000429 at 430); Ex. 16, Hadba Tr. 92:21-94:4. Sight apparently seeks to meet its infringement burden by

excluding Dr. Iwach's analysis of the correct drawing (C00151 Rev. J) and pretending the accused design is other than it is. The Court should reject this attempt and deny Sight's motion.

Sight seeks to bypass these flaws in its argument by characterizing Dr. Iwach's opinion as "lacking a reliable methodology," but Sight identifies nothing "unreliable" about his methods or analysis. In fact, Dr. Downs uses the same method Dr. Iwach used for analyzing the Hydrus drawing: he reviewed the same C00151 drawing (critically, an outdated version) and concluded that "[a]s can also be seen from the Hydrus engineering drawings, the inlet region of the Hydrus is formed to have a smaller radius of curvature." D.I. 298-14 Downs Op. Rep. ¶205. Notably, neither Sight nor Dr. Downs disputes Dr. Iwach's opinion that the current Hydrus drawing (IVANTIS_SS_00000772) depicts a straight transition zone. D.I. 298-16, Downs Reply Rep. ¶¶12-26; *see* D.I. 298-19 ¶ 140; Ex. 14, 9/22/23 Downs Tr. 346:5-21.

Second, Sight's contention that Dr. Iwach ignored contradictory evidence is incorrect. Sight contends the written dimensions on the drawing suggest that the entire transition zone is curved, and further that Dr. Iwach "could not interpret" them (D.I. 291 at 28), but Sight ignores Dr. Iwach's testimony directly addressing those dimensions and explaining that they are, in fact, consistent with his opinion because the arrow Sight relies on does not identify a specific location where the curvature ends. Ex. 17, Iwach Tr. 199:2-200:2. In addition, Dr. Iwach also considered the testimony of Defendants' witnesses, along with the drawing, and concluded that the Hydrus's transition zone is not curved. Ex. 3, Iwach Reb. Rep., Ex. B; D.I. 298-19 ¶¶ 137-141.

Moreover, despite Sight's selective quotes and mischaracterizations of that testimony, none of it contradicts Dr. Iwach's opinion. Sight relies on testimony from two witnesses to argue that manufacturing steps are "not fully reflected in [the Hydrus] schematics," (D.I. 291 at 28), but both witnesses testified directly to the contrary. One witness confirmed the current drawing

(C00151 Rev. J) reflects the shape of the final product after all manufacturing steps have been performed. Ex. 10, Abraham Tr. 273:2-5, 277:9-278:24 (discussing Ex. 40 (Dep. Ex. 62 (C00151 Rev. J)). He further explained that midway through manufacturing, the Hydrus does not yet match the drawing—"[y]ou have to go through all the steps for the part to be its final configuration to meet this drawing."). *Id.* Similarly, the other witness testified the Hydrus is manufactured based on the current drawing (Rev. J), and the final product is inspected for compliance with that drawing. Ex. 19, Kimball Tr. 81:6-82:9. Further, contrary to Sight's implication, Defendants' witnesses never testified that the transition zone is curved. D.I. 291 at 29. In fact, one of the witnesses testified that an older version of the Hydrus drawing depicting a curved transition zone was inaccurate because, in reality, the "inlet area [including the transition zone] is a lot more rigid so it doesn't bend," D.I. 292-10 at 84:18-85:15. This testimony not only supports Dr. Iwach's opinion but also explains why Ivantis revised the drawing to correct the inaccurate older versions (including Rev. G, which Dr. Downs incorrectly relies on).

Similarly, Sight points to testimony that the portion of the Hydrus to the left of a certain vertical line in the drawing ***has*** a curvature (D.I. 291 at 30), but that testimony does not state that the curvature exists along that entire portion of the device (including the transition zone). D.I. 292-9 Hadba Tr. 134:5-20. While Dr. Iwach's opinion is sufficiently supported by the Hydrus's drawing, the testimony Sight identifies largely provides additional support for his opinions, and he is entitled to rely on such testimony at trial. To the extent Sight disagrees, Sight can cross-examine Dr. Iwach on any such evidence. *Godreau-Rivera*, 598 F. Supp. 3d at 206 n.3.

Third, Sight's challenge to Dr. Iwach's ability to interpret an engineering drawing is without merit. D.I. 291 at 27. Dr. Iwach has over 30 years of experience using medical devices to treat glaucoma and he implants minimally invasive glaucoma surgery (MIGS) devices

approximately 5-10 times a month. D.I. 298-19 ¶ 6; Ex. 17, Iwach Tr. 90:15-92:7. He also has four years of education in engineering, D.I. 298-19 ¶ 5; Ex. 17, Iwach Tr. 9:16-21, 11:8-25, and researches, investigates, and develops MIGS devices (often alongside engineers), D.I. 298-19 ¶ 6-10, making him familiar with engineering drawings and MIGS-device geometries, and qualified to assess whether a device satisfies the "arcuate member" term. Moreover, Dr. Iwach is a POSA under each party's proposed definition. D.I. 298-19 ¶¶ 42-44; Ex. 2, Iwach Reb. Rep., Ex. A; D.I. 181 at 4-5; D.I. 298-14 Downs Op. Rep. ¶ 42. Sight does not dispute that as a POSA, Dr. Iwach is qualified to analyze the drawings, specification, and claims of the Asserted Patents, including disclosures of arcuate and straight portions of MIGS devices. Sight fails to identify anything about the Hydrus drawing that requires a higher level of skill to analyze than the Figures in the Asserted Patents. Sight also fails to explain what "engineering principles" one would use to assess whether a surface in a drawing is straight or curved or why Dr. Iwach's engineering education is insufficient. D.I. 291 at 27; *Ruggiero v. Yamaha Motor,* 2017 WL 1197755, at *5 (D.N.J. Mar. 31, 2017); *Yarchak v. Trek Bicycle*, 208 F. Supp. 2d 470, 501 (D.N.J. 2002). Dr. Iwach is qualified to testify to his opinions.

VII. ALCON'S EXPERTS' 30% LIMITATION OPINIONS ARE ADMISSIBLE

Sight argues certain of Dr. Izatt's opinions—and by extension, certain of Dr. Tanna's opinions—rely on models of "straight (i.e., non-arcuate) cylinder[s]," which allegedly result in "conclusions that contradict the Court's claim construction." D.I. 291 at 30-31. Sight does not challenge Drs. Izatt's and Tanna's conclusions that, for most prior art devices, the surface area contact is 0% because the shape of each device creates only point contact (with any cylinder that surrounds it, whether straight or arcuate). Ex. 4, ¶¶66, 69, 106, 139, 144, 150. For certain prior art devices with 0% contact area, Dr. Izatt then used a straight cylinder to perform "***conservative***" calculations (*i.e.*, to maximize potential contact for purposes of analysis) of

surface area contact by "include[ing] surface area that is plainly not contacting the cylinder." Ex. 4, ¶¶66, 69, 106, 144, 150. This analysis is relevant because (1) the surface-area contact is unchanged if the cylinder is straight or arcuate and (2) the surface-area contact calculations are far under 30% even using conservative dimensions, such that minor variations would not change the result. Critically, Drs. Izatt and Tanna use this analysis to find that the prior-art devices meet the 30% limitation ***under the Court's construction***. Even if Sight disagreed with the calculations (it does not), Sight's criticisms go only to weight, not admissibility. *MiiCs & Partners v. Funai Elec.*, 2017 WL 6268072, at *2 (D. Del. Dec. 7, 2017); *Tormenia v. First Invs. Realty*, 251 F.3d 128, 135 (3d Cir. 2000) (expert opinion admissible where there was "ample available means to challenge perceived weaknesses in assumptions underlying [expert's] testimony").

First, Dr. Tanna considered that Dr. Izatt's models were done using a non-arcuate cylinder and concluded that "the same [analysis] would be true if the straight portions of the outlet segments were slightly arcuate and the cylinders were slightly arcuate to match," (*i.e.*, whether the stent and cylinder are both straight, or are both arcuate, the calculation will not change). D.I. 298-17, Tanna Op. Rep. ¶168, 170, 173; Ex. 58 at 17-18; Ex. 59 at 2-5; Ex. 18, 9/27/2023 Izatt Tr. 18:2-11. Mathematically, a torus (*i.e.*, an arcuate cylinder that connects at the ends) has the exact same surface area as a straight cylinder of the same length and cross section. Ex. 58 at 17-18; Ex. 59 at 2-5. Neither Sight nor its experts dispute Dr. Izatt's calculations or Dr. Tanna's opinion that changing the hypothetical cylinder to be slightly arcuate would not have any bearing on the calculations. Far from contradicting the Court's construction, Dr. Izatt's models provide data relevant to his and Dr. Tanna's opinion that the prior art devices do not meet the 30% limitation ***under the Court's construction***. Sight's cases do not support its argument because the experts in those cases offered opinions that did not follow the court's construction.

Integra Lifesciences, 2018 WL 1785033, at *5 (excluding opinion that added additional claim requirements beyond Court's construction); *Liquid Dynamics v. Vaughan*, 449 F.3d 1209, 1224 n.2 (Fed. Cir. 2006) (same); *Minerva Surgical v. Hologic*, 2021 WL 3048447, at *8 (D. Del. July 20, 2021) (excluding opinion that "would completely vitiate the claim limitation").

Second, Dr. Izatt's models are based on dimensions provided by Dr. Tanna. Ex. 4, Izatt Op. Rep. ¶55; Ex. 18, 9/27/23 Izatt Tr. 18:7-11, 21:2-4, 35:5-20, 37:11-22, 42:22-43:7, 48:20-49:1, 57:25-58:8. Dr. Tanna explains that the dimensions he provided and the calculations that follow are meant to be "very conservative" (*i.e.*, overstate the surface contact area under the Court's construction, such that if the calculated value is below 30%, then the surface contact area under the Court's construction is necessarily also under 30%), and that "minor (and in some cases major) variations of these dimensions would not change the overall analysis" because even such conservative dimensions yield surface-area contact below 30%. *See, e.g.*, D.I. 298-17, Tanna Op. Rep. ¶170, 164. Again, Sight does not disagree, and even if it did it could explore any such disagreement on cross examination. *MiiCs & Partners*, 2017 WL 6268072, at *2.

As for Drs. Izatt's and Tanna's opinions that certain prior art devices have 0% surface area contact with Schlemm's canal under the Court's construction (e.g., Ex. 4, Izatt Op. Rep. ¶¶66, 69, 106, 139, 144, 150; D.I. 298-17, Tanna Op. Rep. ¶¶164, 168, 170, 173, 177, 448, 451, 670), Sight's experts do not dispute those opinions, and Sight does not identify any basis to exclude them. Yet Sight's proposed order would exclude portions of the expert reports that contain these ***unchallenged*** 0% opinions. *Id*. Dr. Izatt's models are helpful for the jury to visualize the basis for both experts' 0% opinions (e.g., they show how the addition of ribs to a stent results in solely point contacts with a cylinder wall). For example, certain physical characteristics of these devices (e.g., rounded edges of a wire filament (Ex. 4, Izatt Op. Rep.

¶¶65-69), pointed ribs (*Id.*, ¶¶104-06, 142-44, 148-150), an ovoid structure (*Id.*, ¶¶137-39)) render the surface area contact 0%, and this is true regardless of whether the cylinder is arcuate or straight. Moreover, the 0% opinions are separately admissible because they are also based on analysis, independent of any models, of the interaction between the devices and a hypothetical arcuate cylinder under the Court's construction. Ex. 4, Izatt Op. Rep. ¶¶66, 69, 106, 139, 144, 150; D.I. 298-17, Tanna Op. Rep. ¶¶164, 168, 170, 173, 177, 448, 451, 670). To the extent Sight seeks to exclude the 0% opinions, its motion should be denied.

VIII. SIGHT'S MOTION TO EXCLUDE OPINIONS ON NON-INFRINGING ALTERNATIVES SHOULD BE DENIED

A. Drs. Becker and Iwach's Opinions Are Supported by Sufficient Evidence.

Sight does not dispute that as of 2012, Ivantis had in its possession two Hydrus designs—the "single-radius" Hydrus and the "two-window" Hydrus—that do not infringe the Asserted Patents. D.I. 298-14 ¶359-364, D.I. 298-16 ¶¶83, 85. Alcon's technical expert Dr. Iwach relies on documentation from clinical tests and testing in human cadaver eyes, as well as his years of experience as a glaucoma clinician, to offer his medical opinion that these two non-infringing alternatives ("NIAs") would not be meaningfully different from the commercialized Hydrus in terms of functionality, efficacy, or safety. Alcon's FDA expert, Dr. Becker, relies on Dr. Iwach's opinion, her own review of the same documentation, her years of professional experience, and her review of Ivantis's FDA submissions for the commercialized Hydrus to conclude that had Ivantis implemented the alternative designs in 2012 (or any time before 2017), the NIAs could have been rolled into the ongoing investigational device exemption study and been approved to market in the same timeframe as the commercialized Hydrus. These opinions are squarely within Dr. Iwach's and Dr. Becker's areas of expertise and are supported by evidence of the type reasonably relied upon by experts in their fields. Sight does not contest Dr. Becker's or Dr.

Iwach's qualifications or the "fit" of their testimony. Instead, Sight's argument is premised entirely on Drs. Iwach and Becker's purported failure to review a single type of data. D.I. 291 at 32. Sight's complaint goes to weight, not admissibility, and its motion should be denied.

1. The evidence relied upon by Drs. Iwach and Becker is sufficient and reliable.

Dr. Iwach's and Dr. Becker's opinions are well supported by evidence of the type reasonably relied upon by experts in their respective fields, including clinical data, testing in cadaver eyes, and internal company reports. For example, Dr. Iwach reviewed a report outlining the testing protocol, results, and physician notes of a live four-patient study of the single-radius stent conducted by Dr. Ike Ahmed in 2011. *See* D.I. 298-19 ¶240; Exs. 45-46. Sight argues this evidence is irrelevant because the study was primarily concerned with assessing the Hydrus delivery system, but the study indisputably involved physical implantations of the single-radius Hydrus in live patients and reported no concerns with the safety or efficacy of the device. *See* Ex. 45; Ex. 46 at 390245. Further, as Dr. Becker noted at her deposition, the fact that Dr. Ahmed felt comfortable implanting the single-radius device in multiple live patients (as part of the 22-patient study) is evidence of clinical equivalence. *See* Ex. 13 at 47:6-10, 76:3-18, 96:17-97:3.

In addition to clinical data, Dr. Iwach also relies on internal Ivantis documentation, including a Risk Management Report for the single-radius Hydrus, which provided Ivantis's [redacted] Ex. 44 at 371906. After analyzing the potential risks and benefits of the single-radius design, Ivantis concluded [redacted] further corroborating Dr. Iwach's opinion. *Id*. at 371912; *see also* D.I.

298-19 ¶¶ 245, 248; Ex. 13, Becker Tr. at 62:12-24. Dr. Iwach similarly relies on Ivantis's Non-destructive Functional Test Report for the delivery and use of the single-radius Hydrus, which found [redacted] D.I. 298-19 ¶ 241; Ex. 41 at 371839. And Dr. Iwach relies on Ivantis testing in human cadaver eyes that concluded the single-radius design is [redacted] D.I. 298-19 ¶240 (citing Ex. 46 at 390245).

Dr. Iwach further relies on human cadaver eye testing by Andy Schieber, the lead designer of the Hydrus® Microstent, and by Dr. Gary Condon, a board-certified ophthalmologist and cataract surgeon with over 30 years of experience, which found [redacted] *See* D.I. 298-19 ¶241; Ex. 8 at 435507-10; Ex. 7 at 435566-570. Sight's argument that these tests would not be considered by the FDA because they were conducted in the context of litigation and summarized in expert reports attempts to obfuscate the data's relevance. The data collected by Mr. Schieber and Dr. Condon supports Dr. Iwach's opinion that the NIAs are clinically equivalent to the commercialized Hydrus; the data is not somehow different simply because it was gathered and summarized in a litigation report. *Cf.* Ex. 13, Becker Tr. 53:20-54:1 ("[T]hey're data[ ]based, data driven, so expert opinions sometimes are submitted to the agency."); *see also*, *id*. at 60:11-18. Sight's complaint elevates form over substance.

Sight does not meaningfully dispute the reliability of all this data, instead alleging without support that the FDA would not accept it as proof of clinical equivalence because it concerns testing on human cadaver eyes rather than live patients. *See* D.I. 291 at 37-39. That criticism entirely misses the point. Neither Dr. Iwach nor Dr. Becker opines that such tests alone

would be sufficient for FDA approval. Instead, Drs. Iwach and Becker use the single-radius Hydrus's performance in human cadaver eye tests to show that in the but-for world where Ivantis pursued the single-radius design, the design would have shown clinically equivalent results to the commercialized Hydrus. Sight has not shown why experts in Dr. Iwach's or Dr. Becker's respective fields would not rely on such evidence in this manner. *See Inline Connection v. AOL Time Warner*, 472 F. Supp. 2d 604, 613 (D. Del. 2007) ("Defendants provide no basis that the information [the expert] used in his analysis is inadmissible or not accepted by experts in the industry. Defendants may not agree with his conclusions, but that is not a basis to strike an expert's opinion under FRE 702 or 703.").

It was reasonable for Dr. Iwach to rely upon his years of experience as a glaucoma surgeon and the foregoing evidence to show that in the but-for world, the single-radius design would have shown clinically equivalent results to the commercialized Hydrus because the documents reflect actual performance data from tests of the single-radius Hydrus and Ivantis's own conclusions regarding the functionality, risks, and benefits of the design. Thus, because Dr. Iwach's opinions are evidence-based, they are not *ipse dixit*,[8] and Dr. Becker's reliance upon them is proper. *See Allscripts Healthcare*, 2022 WL 3021560, at *37 (expert's opinions based on experience and evidence are not *ipse dixit*); *EMC Corp. v. Pure Storage*, 154 F. Supp. 3d 81, 115 (D. Del. 2016) ("It is perfectly reasonable for [an expert] to adopt the conclusions of other experts. Whether those conclusions are sound can be explored at trial….").

[8] Sight's cases are inapposite. *Hoefling v. U.S. Smokeless Tobacco* dealt with the question of medical causation—whether smokeless tobacco caused tonsil cancer—where the expert admitted it was "just about impossible" to determine smokeless tobacco's role in oropharyngeal cancer, and yet he drew that conclusion based on his own say-so. 576 F. Supp. 3d 262, 275 (E.D. Pa. 2021). As discussed above, Dr. Iwach's opinion is evidence-based.

2. The 22-patient study does not undermine Drs. Iwach and Becker's opinions.

Sight argues the opinions of Dr. Iwach and Dr. Becker on the clinical equivalency of the proposed NIAs are inadmissible because they allegedly failed to consider underlying clinical data of 22 patients who were implanted with the single-radius Hydrus. *See* D.I. 291 at 32, 35-36 (citing Ex. 56). Sight's argument that Drs. Iwach and Becker should have considered that data is not a basis for exclusion; it is fodder for cross-examination. *See Godreau-Rivera*, 598 F. Supp. 3d at 206 n.3 ("Defendant may cross-examine [expert] on [information the expert failed to consider], but it does not render his opinion inadmissible."); *In re Proton-Pump Inhibitor*, 2022 WL 18999830, at *9 (D.N.J. July 5, 2022) (similar). Moreover, Sight failed to explain how the underlying data for these 22 patients would undermine the reliability of Dr. Iwach's and Dr. Becker's opinions. During his deposition, Dr. Iwach testified regarding statements in a 2012 board presentation about the 22-patient study, concluding [redacted] *See* Ex. 17, at 240:8-244:17.

Sight also repeatedly misquotes Dr. Becker in an attempt to raise a reliability issue where none exists. Sight cherry-picks statements from Dr. Becker's ***background section*** about clinical data in general, divorced from the context of her opinions regarding the single-radius device in this case, to argue the clinical data of the 22 live patients implanted with the single-radius Hydrus was "particularly important," "essential evidence" the FDA would need to consider. *See* D.I. 291 at 34 (citing D.I. 295-19, Becker Rep. ¶50). But this argument for exclusion ignores Dr. Becker's repeated explanations about why additional clinical data would not have been necessary for FDA approval of the NIAs. D.I. 295-19 ¶¶80, 86. Sight also misrepresents Dr. Becker's

testimony, alleging she admitted the FDA would not approve the single-radius design absent the underlying data from the 22-person study. *See* D.I. 291 at 34. In fact, she testified to the contrary:

> Q. But you would agree with me that without seeing the data on the 22 patients who were implanted with the single radius design, you can't say what the FDA might or might not require. Right?
>
> A. ***I did not say that. I did not say that.***

Ex. 13 at 97:8-13. Dr. Becker actually testified she would expect such information to be submitted to the FDA if it ***were relevant***, not that it would change the regulatory pathway for either NIA. *Id.* 99:17-100:15. Indeed, as Dr. Becker explained, additional clinical data is not always required for FDA approval, particularly where—as here—the modification is minor with respect to a device that already has been clinically validated. D.I. 295-19 ¶¶46-49; *id*. ¶20. Dr. Becker explained that, "given the extensive clinical validation of [the Hydrus] technology, a[n FDA] requirement for additional clinical trials is unlikely." Ex. 13 at 17:24-18:5; *see also id*. 30:21-31:23, 32:24-33:2, 105:1-21 ("[T]he products would have comparable safety profiles, and that's based on the accumulated experience over many years in the clinic and a direct comparison of the two products in bench testing and this preliminary clinical data.").

Sight's cases also do not support exclusion. Sight points to *Pugh v. Community Health Systems*, a medical malpractice case that concerned an expert who opined about the cause of a patient's autism but failed to consider literature suggesting other causes. 2023 WL 3361166 at *12-14 (E.D. Pa. May 10, 2023). The expert further failed to demonstrate the factor at issue could cause autism at all, let alone that it actually did in that case. *See id.* at *14 ("[T]he Court finds—particularly in light of [the expert's] unwillingness to explicitly provide HIE/NE ***can cause*** autism/ASD—[the expert's] proffered opinion … is an inadmissible 'unsupported speculation.'") (emphasis in original). Here, Dr. Iwach and Dr. Becker are not offering

unsupported opinions on medical causation while failing to consider other possible causes (causation is not an issue in this case), nor did they ignore data purportedly contrary to their opinions. In fact, Dr. Iwach considered the evidence Sight claims is "contrary," [redacted] *See* D.I. 298-19 ¶245 (citing Ex. 44). Dr. Iwach also addressed this purportedly "contrary evidence":

[redacted]

Ex. 17 at 243:13-20. As noted in Dr. Iwach's report, "about 14% of patients using the commercialized Hydrus® Microstent experience PAS," which is [redacted] *See* D.I. 298-19 ¶245; D.I. 291 at 37. Unlike in *Pugh*, Sight cannot point to anything in the 22-patient study of the single-radius Hydrus that undermines Dr. Iwach's opinion. *Pugh*, 2023 WL 3361166, at *12-14. If Sight takes issue with Dr. Iwach and Dr. Becker not reviewing certain data, Sight can cross them on that point. *See Godreau-Rivera*, 598 F. Supp. 3d at 206 n.3; *In re Proton-Pump Inhibitor*, 2022 WL 18999830, at *9.

Dr. Iwach's and Dr. Becker's opinions are supported by evidence of the type reasonably relied upon by experts in their fields, and Sight's complaints about the sufficiency of that evidence go to weight, not admissibility. *See Masimo Corp. v. Philips Elec.*, 62 F. Supp. 3d 368,

[9] PAS are adhesions between the iris and trabecular meshwork and are the most common complication that arises from surgeries involving the commercialized (accused) Hydrus, yet that did not stand in the way of FDA approval. *See* D.I. 298-19, Iwach Reb. Rep. ¶245.

387-88 (D. Del. 2014) ("Where there is a logical basis for an expert's opinion testimony, the credibility and weight of that testimony is to be determined by the jury, not the trial judge"); *bioMerieux v. Hologic*, 2020 WL 327161 at *2 (D. Del. Jan. 21, 2020) (allowing opinions "based on his extensive experience… and his review of record evidence," noting "Plaintiffs' criticisms go to the weight, not admissibility, of his opinions."). Sight's motion should be denied.

B. Considering Design-Arounds Available Prior to Commercial Launch Is Correct Under the Law.

Sight claims "the law is that the availability of non-infringing alternatives not already on the market is assessed beginning at the date of first infringement—here, August 2018—and no earlier." D.I. 291 at 40. First, Sight is wrong about the date of first infringement: that date is October 2012, when Sight's first asserted patent issued and Hydrus was involved in clinical trials. Ex. 60. Second, there is no rule that NIAs available ***prior to*** the date of first infringement cannot be considered for assessing damages. Thus, whether the date of first infringement is October 2012 (first patent issuance) or August 2018 (when Hydrus commercially launched), Mr. Meyer properly considers the impact of the real-world non-infringing designs Ivantis had available to it in August 2012. Sight's fictitious "rule" has no basis in law. It is Sight's improper attempt to inflate its demands for lost profits and reasonable royalty damages, present a one-sided story to the jury, and prevent Ivantis from responding. Sight's motion should be denied.

1. The date of first infringement is October 2012 and Ivantis had non-infringing designs available as of that date.

Sight contends August 2018 is the date of first infringement because that is when Ivantis obtained FDA approval to commercially launch Hydrus. Ex. 23 at 18-19; D.I. 295-19 ¶4; Ex. 57. Although that is the first ***compensable*** infringement, Ivantis had been making and using Hydrus for years during the term of Sight's patent. Indeed, Sight's CEO Paul Badawi [redacted]

[redacted]

[redacted] At the same time, Sight began drafting claims in subsequent applications to encompass material it did not invent to try to read on Hydrus. D.I. 297 at 1, 13-15. In fact, when the '482 patent issued in 2012, Paul Badawi [redacted] *see* D.I. 298-1, U.S. Pat. No. 8,287,482 ("'482 Patent"). Yet Sight did not even "think" about telling Ivantis of purported infringement of the '482 patent until it filed the Complaint in this litigation ***nine years later***, in 2021. D.I. 298-59, RFA No. 24; Ex. 12 at 90:20-91:1.

Ivantis had non-infringing designs available in 2012, when the '482 patent issued and alleged infringement began (even if exempt from liability under §271(e)'s safe harbor). It made a stent that does not practice Sight's patents, and successfully implanted that stent in humans, facts unrebutted by Sight. D.I. 295-19 ¶¶ 20, 80, 82; D.I. 298-19 ¶¶228, 256; Ex. 61, Schultz Tr. 157:14-24. Although Ivantis ultimately chose to pursue the Hydrus design Sight now accuses, alternate designs were available to Ivantis in 2012. Those facts affect the lost profits and reasonable royalty analyses, as described below.

2. Non-infringing alternatives affect the calculations for lost profits and royalty damages.

Under 35 U.S.C. § 284, a prevailing plaintiff is entitled to "damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer." For lost profits, the proper analysis "requires a reconstruction of the market, as it would have developed absent the infringing product…." *Grain Processing v. Am. Maize-Prods.*, 185 F.3d 1341, 1350 (Fed. Cir. 1999). For a reasonable royalty, the proper analysis determines what the parties would have agreed to *ex ante* in an "arms-length" negotiation between a willing licensor and willing licensee (called a hypothetical negotiation,

which applies only in the reasonable royalty context). *Lucent Techs. v. Gateway*, 580 F.3d 1301, 1324 (Fed. Cir. 2009). If the defendant developed or could readily have developed its own NIA ***before*** the accused conduct began, that is relevant to both forms of damages, albeit for different reasons that Sight's motion conflates. In the lost profits context, if the defendant had an NIA available, the plaintiff generally cannot show the infringement caused it to lose profits because "a rational would-be infringer is likely to offer an acceptable noninfringing alternative, if available, to compete with the patent owner rather than leave the market altogether." *Grain Processing*, 185 F.3d at 1351. Importantly, a non-infringing alternative need not have actually been on the market to be considered. *Id.* at 1350-51. Likewise, in the reasonable royalty context, the availability of an NIA may reduce the amount of royalties to which the parties would have agreed in a hypothetical negotiation. "[A] party may ... estimate the value of the benefit provided by the infringed features by comparing the accused product to non-infringing alternatives." *Apple v. Motorola*, 757 F.3d 1286, 1315 (Fed. Cir. 2014), overruled on other grounds by *Williamson v. Citrix Online*, 792 F.3d 1339 (Fed. Cir. 2015).

Consistent with Federal Circuit precedent, Alcon's damages expert considers Ivantis's non-infringing designs in his analyses of lost profits and royalty damages. In his opinion, these non-infringing designs are relevant to how "the market would have developed absent the infringing product" and show Sight suffered no lost profits. D.I. 298-13 ¶¶105-106. He also opines these designs would have affected a hypothetical negotiation over a reasonable royalty in 2018 because the cost of implementing these designs acts as a proxy for the ***incremental value*** of Sight's patents—as opposed to awarding "hold-up" value due to costs incurred as a result of regulatory delay (*see infra*). *Id.* ¶¶160-162. Mr. Meyer's opinions comport with the law and the jury should be permitted to hear his testimony.

3. Mr. Meyer's lost profits analysis properly evaluates non-infringing alternatives available to Defendants during the period of infringement.[10]

A lost-profits analysis "requires a reconstruction of the market, ***as it would have developed absent the infringing product***, to determine what the patentee would . . . have made." *Grain Processing*, 185 F.3d at 1350. "[O]nly by comparing the patented invention to its next-best available alternative(s) — ***regardless of whether the alternative(s) were actually produced and sold during the infringement*** — can the court discern the market value of the patent owner's exclusive right, and therefore his expected profit or reward, had the infringer's activities not prevented him from taking full economic advantage of this right." *Id*. at 1351.[11]

Ivantis's successfully implanted, non-infringing 2012 design is relevant and necessary to give an accurate picture of the "market as it would have developed" absent infringement. *Grain Processing*, 185 F.3d at 1350. In 2012, when the '482 patent issued, Hydrus was in clinical trials. Those trials would otherwise be infringing acts, but they are exempted from liability under 35 USC 271(e)(1)'s safe harbor. *See REGENXBIO v. Sarepta Therapeutics*, 2022 WL 609141, at *2 (D. Del. Jan. 4, 2022) ("271(e)(1) is an affirmative defense."); *Galderma Labs. v. Medinter US*, 2020 WL 871507, at *3 n.2 (D. Del. Feb. 14, 2020); *Classen Immunotherapies v. Somaxon Pharms.*, 2013 WL 9947386, at *2 n.1 (C.D. Cal. Apr. 11, 2013) (same). Thus, October 2012 is the date of ***first*** infringement. August 2018 is merely the first ***compensable*** infringement because

[10] As discussed above, the opinions of Drs. Becker and Iwach are reliable and supported, and Mr. Meyer's reliance on them is reasonable. *See EMC Corp.*, 154 F. Supp. 3d 81, 115.

[11] The *Grain Processing* court cited several secondary sources explaining why, economically, treatment of non-infringing alternatives is necessary in order for lost profits to approximate the value of the purported invention. *See Grain Processing*, 185 F.3d at 1351 ("The infringer should have a chance to argue what he or she might have done in the absence of infringement. Obviously, if the defendant is not permitted to present evidence of this ilk, the analysis is quite skewed: only the patentee's 'best case' scenario is presented, rather than a more realistic scenario.").

it is when Hydrus received FDA approval for commercial launch and when Sight contends it began losing profits. In 2012, when the '482 patent issued—or even as late as 2017—Ivantis could have pursued one of the alternative designs it had already made ***and already implanted successfully in humans*** and not lost any time launching a commercial product by August 2018. That is relevant under *Grain Processing*, which requires that "a fair and accurate reconstruction of the 'but for' market also must take into account, where relevant, ***alternative actions the infringer foreseeably would have undertaken had he not infringed***." *Grain Processing*, 185 F.3d at 1350-51. Moreover, in *Grain Processing*, the court affirmed the district court's denial of lost profits based on a non-infringing alternative that was available more than two years ***before*** the first compensable infringement. *Id.* at 1348, 1351.[12] Mr. Meyer's opinions comport with the law, and his opinions should not be excluded.

Sight relies primarily on *Apple v. Samsung* to argue for a rule that would cut off evidence of non-infringing alternatives if the evidence predates the first compensable infringement. Sight's motion distorts that case, which addressed different issues and does not support Sight's purported rule. In *Apple v. Samsung*, although the district court said "design arounds must be considered ***beginning*** on the date of first infringement," that was in the context of considering a plaintiff's argument for a ***later*** date—when notice occurred. 2013 WL 5958172 at *1 (N.D. Cal. Nov. 7, 2013). The court was not asked to exclude evidence of ***earlier*** design-arounds. As *Apple* explained (citing Federal Circuit precedent), "an accurate lost profits analysis necessarily considers the full course of infringement," 2013 WL 5958172, at *3, and "pre-notice

[12] Sight does not rely on the statement in *Grain Processing* at 1563, and it should not do so for the first time in its reply. *See generally*, D.I. 291. In that section of its opinion, the Federal Circuit did not rewrite its preceding, lengthy discussion of how to construct "a fair and accurate reconstruction of the 'but for' market." It addressed the procedural burdens of the parties in addressing non-infringing alternatives.

infringement is still infringement." *Id.* at *4–5. The *Apple* court emphasized that the Federal Circuit ***barred*** lost profits in *Grain Processing* "[b]ecause American Maize had a noninfringing alternative 'available' to it ***over two years before Grain Processing became eligible to receive infringement damages***." *Id*., at *2 (citing *Grain Processing*, 185 F.3d at 1348).[13] *Apple* supports Defendants, not Sight: *Apple* rejected the plaintiff's attempt to erase early evidence of available non-infringing alternatives, and thereby present an incomplete picture of how the market would have developed. What *Apple* rejected is what Sight is trying to do here. Just as "pre-notice infringement is still infringement" when reconstructing the market for damages purposes, so too are Ivantis's actions during the safe harbor—they are just exempt from liability under an affirmative defense. *See, e.g.*, *REGENXBIO*, 2022 WL 609141, at *2; *Galderma*, 2020 WL 871507, at *3 n.2.

Sight cites *Janssen Biotech v. Celltrion Healthcare*, 239 F. Supp. 3d 328 (D. Mass. 2017), in passing, but that case also supports Defendants, not Sight. *Janssen* determined "the starting date to analyze whether there was a reasonable alternative … was 2009 ***when the patent was issued***," *Janssen*, No. 1:15-cv-10698-MLW, Dkt. 516 (Feb. 24, 2017 Hrg. Tr.) at 76. That was so even though the accused biologic drug did not launch commercially until December 2016. Dkt. 414 at 18. At bottom, by angling to cut off evidence of non-infringing alternatives before 2018, Sight tries to distort the market-reconstruction analysis by taking advantage of the FDA regulatory process. 2018 is when the safe harbor expired, not when the infringement began. Under Sight's purported rule, if an accused device is subject to FDA approval, no non-infringing

[13] In the first *Grain Processing* case, Judge Easterbrook, sitting by designation, analyzed what design-arounds the defendant could have pursued ***when the asserted patent issued in 1974***—even though the damages period did not start until 1979. 893 F. Supp. 1386, 1391 (N.D. Ind. 1995).

alternative is possible—even if a physically complete, successfully tested alternative exists—unless the alternative is FDA-approved. Sight's fictitious "rule" would distort the market-reconstruction analysis by requiring the factfinder to imagine that the accused infringer could not begin the FDA approval process for the alternative until after the safe harbor expires for the accused product. That makes no sense, is contrary to *Grain Processing*, and would systematically "overreward" plaintiffs without regard to their inventive contributions. *Grain Processing*, 185 F.3d at 1351 ("[U]nless the law wishes to systematically overreward patented inventions, it is necessary to inquire about the nature and value of the product that the infringer could have made had he not infringed.").

4. Mr. Meyer's reasonable royalty analysis properly evaluates NIAs available to Defendants to apportion the value of the patented technology.

Sight asserts "the same rule applies" for NIAs in the reasonable royalty context as in the lost profits context, D.I. 291 at 41, claiming consideration of NIAs is "presumed to begin on the date of first infringement, *i.e.*, the date of the hypothetical negotiation." *Id.* That argument conflates distinct concepts. In the lost profits context, courts consider whether the defendant had a design-around available for implementation in lieu of the infringing product. *Grain Processing*, 185 F.3d at 1349. But the reasonable royalty "does not look to what would have happened absent the infringing product, but to what the parties would have agreed upon as a reasonable royalty on the sales made by the infringer." *AstraZeneca v. Apotex*, 782 F.3d 1324, 1334 n.3 (Fed. Cir. 2015); *see also RSB Spine v. DePuy Synthes Sales*, 2022 WL 17084156, at *4 (D. Del. Nov. 18, 2022) (*Grain Processing* applies to lost profits not reasonable royalty); *Salazar v. HTC*, 2018 WL 2033709, at *3 (E.D. Tex. Mar. 28, 2018) ("[NIAs] don't play the same role in a reasonable-royalty determination."). Thus, as one court explained, the Federal Circuit has held that "even though '[t]here was . . . no available and acceptable noninfringing alternative to which [the

defendant] could have switched at the time of the hypothetical negotiation,' the fact that there was a possibility that the defendant 'could have come up with one' was sufficient to justify the district court's ***reduction*** of a blended royalty rate from 11.5% to 7%." *Carnegie Mellon Univ. v. Marvell Tech.*, 2012 WL 3686736, at *4 (W.D. Pa. Aug. 24, 2012) (citing *Mars v. Coin Acceptors*, 527 F.3d 1359, 1373 (Fed. Cir. 2008)). *A fortiori* here, where the non-infringing alternative is not speculative but a real-world alternative design successfully implanted in humans years before the date of the hypothetical negotiation, Mr. Meyer should be able explain how that fact would put downward pressure on the royalty rate.

Sight's purported "rule" would inflate its demand for royalty damages by capturing the value of regulatory delay, which would contravene the goal of a hypothetical negotiation, and violate longstanding apportionment principles. Under Sight's fabricated "rule," Ivantis could not consider designing around the Asserted Patents until August 2018 (the date of first compensable infringement), six years into Ivantis's activities practicing Sight's issued patent. D.I. 291 at 41. In August 2018 (the date of FDA approval) Ivantis would be fully locked in to the accused Hydrus design that was poised to commercially launch. Sight would require the jury to imagine that Ivantis could only then start considering designing around Sight's patents, and that Sight could use the leverage of regulatory delay to extract inflated royalties. D.I. 298-10 ¶¶86, 154. Again, Sight's purported rule has no basis in, and is contrary to, precedent. The hypothetical negotiation "should not be based on any premise that the patent holder had the infringer 'over the barrel' due to infringement that later occurred and, therefore, could extract a premium." *Oracle Am. v. Google*, 798 F. Supp. 2d 1111, 1121 (N.D. Cal. 2011). Yet that is exactly what Sight wants to do under the guise of its "rule": use delays involved in the regulatory framework as leverage to inflate patent value.

Sight's purported rule would violate apportionment principles because the cost of obtaining regulatory approval in 2018 has nothing to do with the value of Sight's patents. 35 U.S.C. § 284 authorizes damages "adequate to compensate ***for the infringement***," which may be royalties "for the use made ***of the invention***." For more than 100 years, the Supreme Court has held that patentees cannot capture ***other*** items unrelated to the incremental value of their invention. Rather, they must "separate or apportion the defendant's profits and the patentee's damages between the patented feature and the unpatented features." *Garretson v. Clark*, 111 U.S. 120, 121 (1884). Such unpatented features include, among others, features that are in the prior art, *Exmark v. Briggs & Stratton*, 879 F.3d 1332, 1347-48 (Fed. Cir. 2018); features that are unclaimed, *Power Integrations v. Fairchild Semiconductor Int'l*, 904 F.3d 965, 977 (Fed. Cir. 2018); manufacturing costs, *Beatrice Foods v. New Eng. Printing & Lithographing*, 899 F.2d 1171, 1176 (Fed. Cir. 1990) (*en banc*); and standardization, *Ericsson v. D-Link Sys.*, 773 F.3d 1201, 1232 (Fed. Cir. 2014). For standard-essential patents, the Federal Circuit disapproved of patentees extracting "hold-up," value, which is "when the holder of a SEP demands excessive royalties after companies are locked into using a standard," in order to "ensure that the royalty award is based on the ***incremental value*** that the patented invention adds to the product, not any value added by the standardization of that technology." *Ericsson*, 773 F.3d at 1209, 1232 (Fed. Cir. 2014) (emphasis original). Sight's attempt to capture the value of the FDA regulatory process is no different from a SEP-holder's attempt to capture the value of an entire technological standard. Like manufacturing costs and the value of a standard, regulatory delay has nothing to do with the patented invention and must be apportioned out of any demand for damages. *See Beatrice Foods*, 899 F.2d at 1176. "Any evidence unrelated to the claimed invention . . . punishes beyond the reach of the statute." *ResQNet v. Lansa*, 594 F.3d 860, 869

(Fed. Cir. 2010).

Accordingly, by valuing the cost to design around in 2012, Mr. Meyer's analysis altogether avoids consideration of "hold up" value due to regulatory delay in 2018. Mr. Meyer therefore opines that because it would have cost Ivantis [redacted] to design around the patents in 2012, "[a]ny additional amount that Sight Sciences seeks to recover as royalties is artificially inflated" and "does not measure the contributions of the Asserted Patents." *Id*. ¶162. To be clear, Mr. Meyer does not contend Ivantis would have implemented the design-around in 2018; rather, he contends that in 2018 when the parties hypothetically meet to discuss the value of the patented technology (separating out the value of anything extraneous to the patents), Ivantis would have benchmarked that value as the cost to design around the patents as of 2012, the date the '482 patent issued (because the cost to design around in 2018 would include "hold-up" value). *Id*. ¶¶161-162, Attachment 14; Ex. 62 at 35:11-25, 101:12-102:24, 134:17-135:21, 151:21-155:1, 162:18-167:20. In this regard, Ivantis's non-infringing alternatives are relevant to multiple *Georgia-Pacific* factors. D.I. 298-13 Attachment 14; *Univ. of Pittsburgh v. Varian Med. Sys.*, 561 F. App'x 934, 947-48 (Fed. Cir. 2014) (*Georgia-Pacific* factors nine, ten, and thirteen assist to evaluate the "incremental value" of "claimed invention").

Sight's argument to preclude Mr. Meyer's opinion regarding NIAs in the reasonable royalty context relies almost entirely on *AstraZeneca v. Apotex*, 985 F. Supp. 2d 452 (S.D.N.Y. 2013). In that case, the court, sitting as factfinder, held that Apotex did not have an available NIA because Apotex had tried ***and failed (multiple times)*** to create non-infringing alternatives during the development of its ANDA product. 985 F.Supp.2d at 499-500. Sight focuses on statements from *AstraZeneca* rejecting Apotex's argument that it could have begun designing around prior to the date of the hypothetical negotiation, suggesting the Federal Circuit "affirmed

that portion of the decision" and "agreed that the date to begin designing around the patent was the date of first infringement (not earlier)." D.I. 291 at 43.

Not so. The Federal Circuit never discussed the "date to begin designing around the patent," and simply held the district court's reasonable royalty award was not clear error or an abuse of discretion. *AstraZeneca II*, 782 F.3d at 1333. Importantly, the Federal Circuit did not endorse any suggestion that AstraZeneca could capture the value of regulatory delay in its damages award. The decision relied instead on the district court's "principal finding" that "the evidence shows that none of Apotex's proposed changes to its infringing formulation were feasible." 782 F.3d at 1335. Although Apotex argued that AstraZeneca had been overcompensated by capturing the value of regulatory delay, the Federal Circuit took care to observe that that aspect of the district court's ruling was an "alternative ground" that "had no effect on the court's damages calculation" because the evidence showed more broadly that "Apotex's prospect of developing its own non-infringing alternative was bleak, with or without a period of FDA delay." *Id.* The ***opposite*** is true here. Here the facts demonstrate Ivantis actually had in hand a non-infringing alternative it had implanted in humans. Ultimately, "[w]hether [NIAs] were available is a question of fact and is not a sufficient basis for the exclusion of Mr. [Meyer's] opinion." *Wonderland Switzerland v. Evenflo Co.*, 2023 WL 5568243, at *5 (D. Del. Jan. 3, 2023).

Sight's reliance on *AstraZeneca*'s discussion of *Hanson v. Alpine Valley Ski Area*[14] is likewise misplaced. Indeed, Sight's statement that "the [*AstraZeneca*] court interpreted the *Hanson* decision to mean that '[t]he hypothetical negotiation is hypothetical in the sense that the

[14] *Hanson* is also inapposite as there the accused infringer argued that the cost of implementing a non-infringing alternative should act as a cap on the reasonable royalty, but Mr. Meyer makes no such claim. *See* 718 F.2d 1075, 1081–92 (Fed. Cir. 1983); Ex. 62 at 134:17–135:21.

negotiation itself is imaginary, not in that it allows the parties to construct an entirely imaginary world that ignores the facts as they existed at the date of infringement,'" D.I. 291 at 42-43 (emphasis omitted), applies to what Sight is trying to do here: ignore the fact that Ivantis actually had non-infringing alternatives available to it as early as October 2012, the date of first infringement. *See AstraZeneca*, 985 F.Supp.2d at 501.

Shure v. ClearOne, cited by Sight, actually supports Mr. Meyer's approach. There the patentee alleged *ClearOne*'s damages expert applied the wrong hypothetical negotiation date because she "rel[ied] on data about possible ClearOne alternative designs drawn from a time period ***prior*** to the hypothetical negotiation date[.]" 2021 WL 7209740 at *5 (D. Del. Oct. 5, 2021). The Court rejected that argument, holding there "is nothing inappropriate about" the expert's discussion of "several options for non-infringing [alternatives]" that were drawn "***prior*** to the hypothetical negotiation date," and that those ***earlier*** options were relevant to "what non-infringing design paths ClearOne would have considered ***at the time of the [hypothetical] negotiation***." *Id*. Mr. Meyer's analysis mirrors the analysis found permissible in *Shure*. He does not challenge Mr. Jarosz's opinion that the hypothetical negotiation date is August 2018, based on the first commercial sale of Hydrus, but he properly accounts for the real-world non-infringing design paths Ivantis would have considered at that hypothetical negotiation to benchmark the value of the Asserted Patents (instead of valuing the hold-up associated with changing paths on the date Ivantis received regulatory approval for the accused Hydrus design). Ex. 62 at 35:11-25, 101:12-102:24, 151:21-155:1, 162:18-167:20; D.I. 298-13 ¶¶161-162. In arriving at these opinions, Mr. Meyer relies on Dr. Iwach's opinion that the design-arounds are clinically equivalent to the commercialized Hydrus, and on Dr. Becker's opinion that Ivantis could have switched to either design-around during the FDA approval process without impacting

Hydrus's commercial launch date. D.I. 298-13 ¶¶105-106, 160-162, D.I. 295-19 ¶80. Just as in *Shure*, there is "nothing inappropriate" about this analysis. 2021 WL 7209740 at *5. At best, Sight's arguments go to the weight of Mr. Meyer's opinions and fail to overcome Rule 702's "liberal policy of admissibility." *Bd. of Regents Univ. of Tex. v. Boston Sci.*, 2022 WL 17584180, at *328 (D. Del. Dec. 12, 2022). Sight's motion seeks to silence Alcon's experts from presenting facts about non-infringing alternatives that existed in the real world in order to inflate damages in violation of Federal Circuit precedent. Its motion should be denied.

IX. SIGHT'S MOTION TO EXCLUDE MR. KUNIN'S OPINIONS SHOULD BE DENIED BECAUSE HIS OPINIONS WILL BE HELPFUL TO THE TRIER OF FACT AND HE IS QUALIFIED TO GIVE THEM.

Sight's expert, Dr. Downs, opines that certain prior art references relevant to the Asserted Patents were "considered" by the U.S. Patent & Trademark Office ("PTO").[15] In response, Alcon's expert, Mr. Kunin—former PTO Deputy Commissioner for Patent Examination Policy—explained that there was insufficient evidence to support Dr. Downs's opinion. Sight now improperly seeks to exclude Mr. Kunin's testimony, preferring Dr. Downs's speculation go to the jury unchallenged. Sight concedes Mr. Kunin is well qualified to offer his opinions, but claims he provides improper legal opinions that are unresponsive, contradict precedent, and otherwise "will not be helpful." D.I. 291 at 46-50. But Mr. Kunin opines only on PTO practice and procedure, responds directly to Dr. Downs's unqualified opinions on the same, and presents opinions consistent with the PTAB's *Advanced Bionics* decision and helpful to the jury.

First, Sight incorrectly claims Alcon proffers Mr. Kunin as a "legal expert," so he should

[15] Alcon moved to exclude Dr. Downs's PTO procedure opinions, as he is admittedly not "an expert on patent and trademark office procedures." *See* D.I. 298-23 at 41:20–22; D.I. 294 at 22–23. If the Court grants Alcon's motion, Alcon does not intend to call Mr. Kunin at trial, and the Court should deny Sight's motion to exclude Mr. Kunin's opinions as moot.

be excluded. D.I. 291 at 46. To the contrary, Courts routinely permit patent law experts, like Mr. Kunin, "to testify about matters such as general practices and procedures employed by the PTO in examining or reexamining patents." *Sonos v. D & M Holdings*, 297 F. Supp. 3d 501, 511 (D. Del. 2017) (collecting cases). Mr. Kunin provides opinions consistent with his expertise (including ten years as the Deputy Commissioner for Patent Examination Policy): he explains PTO examination practices and procedures in response to Dr. Downs's unqualified opinions that the examiner "considered" certain prior art during prosecution. *See e.g.,* D.I. 295-31 ¶¶5, 10, 32-38, 52-58, 64-69. Courts routinely admit this type of testimony. *Sonos*, 297 F. Supp. 3d at 511; *W.L. Gore & Assocs., v. C.R. Bard*, 2015 WL 12815314, at *3 (D. Del. Nov. 20, 2015) ("PTO practices and procedures" testimony permissible).

Second, Sight's argument that "Mr. Kunin's opinions are not responsive to any opinions" is wrong. D.I. 291 at 48. Dr. Downs opined in his Rebuttal Report that prior art references in Dr. Tanna's Opening Report "are the same as or substantially the same as references presented to the [PTO] during prosecution." D.I. 298-15 ¶¶98, 101-106. Dr. Downs concluded that the PTO examiner "considered" those references based on his unqualified "interpret[ation]" of the prosecution history. *Id*. at ¶100 ("I would interpret that to mean the examiner did consider the reference."); *see also id.* at ¶¶101-110. Dr. Downs admits he is "not an expert on patent and trademark office procedures." D.I. 298-23 at 41:20-22. Mr. Kunin, on the other hand, relies on decades of PTO expertise to rebut Dr. Downs's speculative opinions.[16] For example, Mr. Kunin responds to Dr. Downs's unqualified "interpretation," explaining that simply because a reference appears in a search query does not necessarily mean the reference was substantively reviewed by

[16] Dr. Downs's "[s]peculation about the thought processes or reasoning of the examiner is inadmissible" and should be excluded. *See* D.I. 294 at 22–23; *Abbott Biotech. v. Centocor Ortho Biotech*, 2014 WL 7330777 at *8 (D. Mass. Dec. 19, 2014).

the examiner. *E.g.*, D.I. 295-31 ¶¶33, 81, 84-85. Sight's contention that Mr. Kunin opines that the PTO "did not substantively review prior art references at-issue," is thus incorrect. D.I. 291 at 47. Mr. Kunin merely opines that there is ***insufficient evidence to conclude*** the references were substantively reviewed, contrary to Dr. Downs's speculative opinion that they ***were*** "considered." *See* D.I. 295-31 ¶¶74, 80-81, 85, 89, 92-93, 98, 116, 119; D.I. 298-15 ¶¶100-110. Sight also insinuates that there is something improper about Mr. Kunin's testimony being offered on reply. *See* D.I. 291 at 47. Not so: a reply opinion, like Mr. Kunin's, that "contradict[s] or rebut[s] evidence on the same subject matter identified by the opposing party's expert report" is proper. *Cirba v. VMware*, 2023 WL 6799267 at *5 (D. Del. Mar. 30, 2023).

Third, Sight contends Mr. Kunin's opinions are "misleading" because they purportedly conflict with the PTAB's *Advanced Bionics* decision regarding when a reference was "previously presented" to the patent office for the purposes of 35 U.S.C. § 325(d) ("325(d)"). *See* D.I. 291 at 47-48 (citing *Advanced Bionics v. Med-El Elektromedizinische Geräte*, IPR2019-01469, Paper 6, 8 (PTAB Feb. 13, 2020) (precedential)). Mr. Kunin, however, ***applied*** *Advanced Bionics*: "I will only discuss Part 1 of the *Advanced Bionics* framework in this report, as Dr. Downs only addressed whether the prior art was considered by the examiner."[17] D.I. 295-31 ¶¶49-52. Indeed, Sight's argument illustrates why Mr. Kunin's opinions are proper and necessary: Dr. Downs, and Sight in its Motion, conflate the PTAB's standard for "previously presented" under 325(d) with an examiner substantively considering a reference. D.I. 291 at 48. They are not the same. The

[17] Sight criticizes Mr. Kunin for identifying the split among PTAB panels regarding what is sufficient consideration of a reference to qualify as "previously presented" for purposes of 325(d). D.I. 291 at 48. This criticism irrelevant—Mr. Kunin does not rely on this split for his opinions—and Mr. Kunin is correct about the split. *See Quasar Science LLC v. Colt Int'l Clothing, Inc.*, IPR2023-00611, Paper 10, 14 (PTAB Oct. 10, 2023) (discussing the distinction between "previously presented" and "substantively addressed" in context of 325(d) analysis).

PTAB may consider a reference "previously presented" for the purposes of 325(d) with as little as a mention in a search query or IDS. D.I. 295-31 ¶¶54-58. Mr. Kunin explained how this differs from an examiner substantively considering a reference by applying it against the claims of a patent, which "is not a prerequisite to a finding that such reference was already presented to the Office under § 325(d)." *Id.* ¶58; *see also id.* ¶61 (describing difference in context of PTAB's proposed rule change), ¶¶79-81. Sight (through Dr. Downs's opinion) asserts that the PTO substantively considered the references at issue (when Sight has no evidence the PTO did that) to ***improperly*** suggest Alcon's burden to prove invalidity is higher. *Sciele Pharma v. Lupin*, 684 F.3d 1253, 1260 (Fed. Cir. 2012) ("Whether a reference was previously considered by the PTO, the burden of proof is the same: clear and convincing evidence of invalidity."). Mr. Kunin's opinions will help the jury understand the nuances of the PTAB rules that Sight has muddled.

Fourth, Sight is wrong that Mr. Kunin's opinions regarding the PTAB's proposed rule change are "speculat[ive]" and thus "no help to the factfinder." *See* D.I. 291 at 49. On April 21, 2023, the PTAB proposed a change to what would constitute "previously addressed" within the meaning of 325(d), such that the application would be limited to where "the [PTO] evaluated the art or arguments ***and articulated its consideration of the art or arguments in the record***." *See* D.I. 295-31, Kunin Rep. at ¶61. The proposed rule change notes that "mere citation" on an IDS or in search results would not be sufficient. *Id*. By contrast, the PTAB's current application of 325(d) requires only "mere citations" for the reference to count as "previously presented." *Id*. at ¶¶54-58. Mr. Kunin's opinions rebut Dr. Downs's improper insinuation that the examiner substantively "considered" the references at issue by illustrating what the PTAB meant when it determined the references were "previously presented" under 325(d), and how the PTAB considers that to be different from substantive consideration. Ex. 20, Kunin Tr. 46:13-48:9.

Fifth, Mr. Kunin unequivocally rejected Sight's contention that he "suggests that the PTO failed to do its job in this case and seeks to undermine the presumption of validity." *Id.* at 96:11-17 ("I didn't say anything like that in my report."); D.I. 291 at 50. Sight's reliance on *Shire Viropharma* is therefore inapposite as Mr. Kunin is not offering any opinions "impermissibly attacking [the] presumption of validity." D.I. 291 at 50. Mr. Kunin acknowledged "[t]he burden of establishing invalidity remains on the party asserting invalidity" regardless of a reference's consideration by the PTO. *See* D.I. 295-31 ¶27. Mr. Kunin's statement is an accurate recitation of the law, *Sciele Pharma*, 684 F.3d at 1260, and experts may "set forth the legal definitions [they] appl[y] in reaching [their] conclusions." *Voter Verified v. Premier Election Sols.*, 2011 WL 87306 at *4 (M.D. Fla. Jan. 11, 2011), *aff'd*, 698 F.3d 1374, 1384, n. 6 (Fed. Cir. 2012).

In short, Mr. Kunin's directly responsive opinions on PTO practice and procedure provide necessary, helpful testimony for the jury should Dr. Downs be permitted to provide PTO opinions at trial. Sight's disagreement with Mr. Kunin's opinions is grounds for cross-examination at trial, not exclusion. *United States v. Mitchell*, 365 F.3d 215, 244 (3d Cir. 2004) (expert testimony "should be tested by the adversary process" when it rests on good grounds).

X. CONCLUSION

For the above reasons, Sight's Motions should be denied.

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CERTIFICATE OF SERVICE

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